

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

RONNIE JONES, ET AL., v. CITY OF BOSTON, ET AL.,)) Plaintiffs,))) Defendants.)))))))) CIVIL ACTION NO. 05-11832-GAO <u>HEARING REQUESTED</u>
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**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL
PSYCHEMEDICS CORPORATION TO PRODUCE DOCUMENTS**

BACKGROUND

On November 3, 2006, plaintiffs served a Rule 45 subpoena on Psychemedics Corporation (“Psychemedics”) requesting that it provide forty-one categories of relevant documents. Almost a year later, and despite repeated representations of Psychemedics that it would produce documents, not a *single* document has been produced.

The detailed background concerning the relationship of Psychemedics to the parties and plaintiffs’ efforts to gather documents from Psychemedics is set forth in the May 15, 2007 Memorandum in Support of Plaintiffs’ Motion to Compel Psychemedics Corporation to Produce Its Standard Operating Procedures (Docket # 42, the “Motion to Compel SOPs”). On page 2, footnote 2 of the Motion to Compel SOPs, Plaintiffs described the status of document production by Psychemedics’s with respect to documents other than the Standard Operating Procedures (“SOPs”) that plaintiffs requested in the November 3, 2006 subpoena to Psychemedics (attached as *Exhibit A* to the Motion to Compel SOPs):

As set forth in an April 13, 2007 letter from plaintiffs’ counsel to counsel for Psychemedics following an April 11, 2007 meet-and-confer conference call [attached to the Motion to Compel SOPs as *Exhibit B*], Psychemedics has agreed to produce documents that would satisfy many of plaintiffs’ document requests.

However, Psychmedics still has not produced any of these documents. During the same meet-and-confer discussion, Psychmedics's counsel agreed to reconsider many of its objections to plaintiffs' document requests. In the event that Psychmedics either refuses to produce the documents it agreed to produce on April 11, 2007 and/or refuses to produce sufficient documents in response to the requests it has agreed to reconsider, plaintiffs reserve their rights to file another motion to compel, seeking an order directing Psychmedics to produce documents and information in addition to the SOPs.

On May 31, 2007, plaintiffs' counsel sent to counsel to Psychmedics a letter concerning the failure of Psychmedics to produce any of the documents that it agreed to produce on April 11, 2007. A copy of this letter is attached hereto as ***Exhibit 1***. The May 31, 2007 letter specifically requested that Psychmedics's counsel inform plaintiffs' counsel of the status of Psychmedics's document production by June 4, 2007. Psychmedics has not produced a single document in response to plaintiffs' Rule 45 subpoena and counsel has not responded to the letter.

Plaintiffs have waited until the conclusion of Stage I Fact Discovery to file this motion based on Psychmedics's representation, in April 2007, that it would produce documents. It is now clear, however, that Psychmedics has no intention of producing responsive documents. Psychmedics's flawed, imprecise, unreliable, arbitrary, and racially biased drug test performed on hair samples (the "Hair Test") is at the heart of this civil rights action, *see Motion at 1-3 and 6-10*, and Psychmedics has no excuse for completely ignoring its obligations under Rule 45 of the Federal Rules of Civil Procedure.

ARGUMENT

Both the state and federal courts have recognized the fundamental principle that the public has the right to every man's evidence. *Brazburg v. Hayes*, 408 U.S. 665, 688 (1972); *see United States v. Nixon*, 418 U.S. 683, 709 (1974) ("The need to develop all relevant facts in the adversary system is both fundamental and comprehensive."); *In re Roche*, 411 N.E.2d 466, 473 (Mass. 1980) (invoking principle that the need to develop all relevant facts is fundamental to adversary system). "Exceptions to the demand for every man's evidence are not lightly created nor expansively construed, for they are in derogation of the search for truth." *Nixon*, 418 U.S. at 710. This general principle is embodied in Federal Rule of Civil Procedure 26(b)(1), which

provides that “[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things and the identity and location of persons having knowledge of any discoverable matter.” The documents described below are directly relevant to this litigation and must be produced.

A. Request 1: “All documents and communications between Psychededics and Defendants.”

As set forth in the April 13, 2007 letter (attached as *Exhibit B* to the Motion to Compel SOPs), Psychededics agreed to produce its contracts with the defendants, all communications related to its contracts with the defendants, and any general communications with the defendants.¹ While Psychededics did not agree to produce individual test results for all of the defendants’ employees who have ever taken the Hair Test based on its representation that it would be burdensome to undertake such a search, counsel to Psychededics agreed to determine whether Psychededics had records confirming the total number of tests it has performed for the defendants, and, if there were any such summary documents (e.g., billing records), Psychededics agreed to produce them.²

¹ Similarly, Request 22 seeks: “All documents and communications concerning any contract, agreement, or other document concerning the terms of the relationships between Psychededics and the Defendants, including but not limited to documents concerning the negotiation, drafting, or performance of such contracts, agreements, or other documents.” During the meet-and-confer, Psychededics agreed to produce the documents that are responsive to Request 22, but Psychededics has not produced any such documents.

² Similarly, Request 36 seeks: “All documents and communications concerning the race, hair texture, hair color, and test result of Boston Police Department personnel who were tested for drugs, including cocaine, on the initial hair and/or safety-net hair test(s).” During the meet-and-confer, Psychededics’s counsel represented that Psychededics never records the race of a person whose hair sample it is testing. Counsel stated, however, that he thought Psychededics could locate some summary documents (e.g., billing records) concerning the total number of tests and that, if such summary documents were available, Psychededics would produce them. Psychededics has neither produced any such summary documents, nor informed plaintiffs whether such documents exist.

To date, Psychemedics has not produced any documents in response to Request 1. Nor has Psychemedics informed plaintiffs whether summary documents concerning the total number of tests it has performed for the Boston Police Department (“BPD”) exist. Therefore, plaintiffs request that the Court order Psychemedics to produce:

- all of Psychemedics’s contracts with the defendants;
- all communications related to Psychemedics’s contracts with the defendants;
- any communications with the defendants;
- any documents summarizing the total number of tests Psychemedics has performed for the BPD; and
- all documents and communications concerning any contract, agreement, or other document concerning the terms of the relationships between Psychemedics and the defendants, including but not limited to documents concerning the negotiation, drafting, or performance of such contracts, agreements, or other documents.

The requested documents, which Psychemedics previously agreed to produce, are highly relevant to this case and Psychemedics has no excuse for continuing to withhold them. Psychemedics’s contracts with the defendants and documents concerning those contracts are relevant because they will show, among other things, how much Psychemedics has been compensated by the defendants and perhaps whether Psychemedics is funding the defendants in this litigation. Moreover, several of the defendants’ current and former employees have testified that the defendants have relied on information provided by Psychemedics to determine that the Hair Test is reliable, accurate, and legally defensible. The requested documents will help plaintiffs demonstrate that Psychemedics has a strong financial incentive to provide biased information to the defendants concerning the reliability, accuracy, and legal defensibility of the Hair Test.

Similarly, documents concerning general communications between Psychemedics and the defendants are relevant to this litigation because these communications will allow plaintiffs to discover the basis, if any, for defendants’ determination that the Hair Test is reliable, accurate, and legally defensible. For example, attached hereto as ***Exhibit 2*** are internal memoranda prepared by Robert Boyle, one of the defendants’ employees, describing communications

between Psychemedics's employees and the defendants' employees concerning the Hair Test process and the accuracy, validity, and legal defensibility of the Hair Test. The July 8, 1999 memoranda describes a meeting at BPD headquarters attended by six BPD employees and William Thistle and Patrick Kelly of Psychemedics. During this meeting, a BPD employee asked Mr. Thistle "if there was anything to the racial bias claim" concerning the Hair Test. In response, Mr. Thistle provided his opinion that there is no racial bias, stating that "a preference among blacks for cocaine also explains the higher rate of positives for that group," and that "the race bias claim [is] baseless but . . . the media likes controversy so it continues to stir the pot." Plaintiffs have undertaken significant efforts in discovery to understand why the defendants implemented and continue to defend the Hair Test. Psychemedics's communications with defendants are critical to that issue because they reveal, among other things, the baseless, biased, and racist statements that Psychemedics has provided to the defendants to defend the Hair Test. These communications must be produced.

Finally, if available, documents summarizing the total number of tests Psychemedics has performed for the BPD would assist the plaintiffs in performing a disparate impact analysis. The defendants have been able to provide only estimates of the total number of tests performed by Psychemedics. To assess the disparate impact of the Hair Test on officers of color, plaintiffs' expert would need to know the precise number of Hair Tests performed on defendants' employees. If Psychemedics has access to summary records that the defendants do not have access to, then Psychemedics should be required to produce these documents, as it previously agreed to do.

B. Request 2: "All documents and communications between Psychemedics and any present or former agents, servants, employees, attorneys, consultants of the Department of Health and Human Services or the Substance Abuse and Mental Health Services Administration, including, but not limited to, all documents and communications between Psychemedics and Robert Stephenson."

As set forth in the April 13, 2007 letter concerning the meet-and-confer, counsel to Psychemedics inquired whether there was any way to narrow this request. Plaintiffs offered to

narrow the request to responsive documents concerning the proposed federal drug testing guidelines that, if ever adopted, would include hair testing. Counsel agreed to discuss this compromise with Psychemedics, but he never responded to plaintiffs.

The documents sought in Request 2 are highly relevant to this litigation and must be produced. The Substance Abuse and Mental Health Services Administration (“SAMHSA”) has been considering proposed guidelines to test hair samples for drugs as part of the federal drug testing program. Urine testing is the only type of drug testing allowed under the current federal guidelines, and, as discussed below, the proposed hair testing guidelines may never be adopted because of various findings in recent government-funded studies concerning the unreliability of the Hair Test and a high rate of false positives. Nonetheless, plaintiffs anticipate that defendants will defend the Hair Test by relying on the proposed hair-testing guidelines.

The requested documents will demonstrate what role Psychemedics played in drafting the proposed guidelines. For example, attached hereto as ***Exhibit 3*** is an April 4, 2002 facsimile from Ray Kubacki, the CEO of Psychemedics, to Robert Stephenson, the director of workplace programs at SAMHSA. In this fax, Mr. Stephenson forwarded “2 pages from the current draft of the Guideline revisions.” He also stated: “You will see that the cutoff are exactly as requested by the industry working group.” (Emphasis in original.) As set forth on pages 9-10 of the Motion to Compel SOPs and pages 3-4 of plaintiffs’ Reply Memorandum in Response to Defendants’ Opposition to Plaintiffs’ Motion to Compel Production of Positive Hair Test Results And E-Mails Responsive to Plaintiffs’ Document Requests (Docket # 57), plaintiffs maintain that the cut-off levels for the Hair Test are inadequate to address the problem of external contamination as the source of a positive result on the Hair Test. The government-funded study described below confirmed that Psychemedics’s cut-off level resulted in a 38% “false-positive” rate, even after wash procedures (including Psychemedics’s wash procedures) were used to decontaminate externally contaminated hair samples of non drug users. Plaintiffs seek the requested documents to understand what role Psychemedics played in drafting the proposed guidelines.

C. Request 3: “All marketing materials concerning Psychededics’s Hair Testing.”

As set forth in the April 13, 2007 letter concerning the meet-and-confer, counsel to Psychededics represented that it would be very burdensome to gather and produce all of Psychededics’s marketing materials. However, during the meet-and-confer, counsel agreed to produce all marketing materials that it has sent to the defendants. As discussed above, the defendants have relied on Psychededics to determine that the Hair Test is accurate, reliable, and legally defensible. The requested documents concern the basis for defendants’ reliance on Psychededics, and Psychededics has no excuse for continuing to withhold these documents that it previously agreed to produce. Therefore, plaintiffs request that the Court order Psychededics to produce all marketing materials concerning Psychededics’s Hair Test that Psychededics has sent to the defendants.

D. Request 4: “All documents and communications concerning the Plaintiffs, the Hair Test, the Defendants, or the Hair Specimens.”

As set forth in the April 13, 2007 letter concerning the meet-and-confer, in addition to documents that Psychededics agreed to produce in response to other requests, Psychededics had already collected and agreed to produce responsive documents concerning each of the individually named plaintiffs.³ Any documents that Psychededics has concerning the individually named plaintiffs in this litigation are unquestionably relevant to this litigation. Moreover, Psychededics gathered the documents it had concerning the individually named plaintiffs more than four months ago with the apparent intent of producing these documents.

³ Similarly, Request 24 seeks: “All documents sufficient to identify the particular facilities and persons involved in the Hair Tests performed on samples taken from the Plaintiffs, including the location of sampling, storage, and testing facilities; the names, affiliations, employment status, and whereabouts of all persons who collected, handled, transmitted, tested, processed, prepared, or analyzed plaintiffs’ Hair Specimens, and all persons who were involved in record-keeping, data collection, analysis, interpretation or reporting of test results.” During the meet-and-confer, Psychededics’s counsel stated that Psychededics had collected responsive documents concerning each of the individually named plaintiffs. Psychededics’s counsel also agreed to produce these documents, but Psychededics has not produced any responsive documents.

Psychemedics has no excuse for continuing to withhold documents concerning the individually named plaintiffs. These documents must be produced.

E. Requests 11-14: Documents And Communications Concerning Psychemedics's Support of "Independent" Hair Testing Studies

Request 11 seeks: "All documents and communications concerning Psychemedics's funding of, sponsorship of, or other contribution to any study concerning the scientific validity of testing hair to detect drugs of abuse, including, but not limited to, documents and communications concerning Psychemedics's funding of, sponsorship of, or other contribution to any study concerning whether the testing of hair to detect drugs of abuse, including cocaine, depends on the race of the person tested and/or his or her hair color or hair texture. The time period for this request is January 1, 1994 to the present." During the meet-and-confer, Psychemedics's counsel agreed to produce the documents responsive to this request.

Request 12 seeks: "All documents and communications concerning Psychemedics's funding of any organization or entity that concerns itself with the testing of hair to detect drugs of abuse, including cocaine. The time period for this request is January 1, 1994 to the present." During the meet-and-confer, Psychemedics's counsel agreed to produce the documents responsive to this request.

Request 13 seeks: "All documents and communications concerning Psychemedics's funding of travel and expenses for any university professor or other scholar to attend a conference concerning the testing of hair to detect drugs of abuse, including cocaine. The time period for this request is January 1, 1994 to the present." During the meet-and-confer, Psychemedics's counsel agreed to produce the documents responsive to this request.

Request 14 seeks: "All documents concerning Psychemedics's funding of any scientific journals. The time period for this request is January 1, 1994 to the present." During the meet-and-confer, Psychemedics's counsel represented that Psychemedics had no documents responsive to this request. Plaintiffs agreed to withdraw the request if Psychemedics would confirm this representation in writing. Psychemedics has not done so.

The documents and communications requested in Requests 11-14 concern Psychemedics's financial support for "independent" studies concerning hair testing. Although defendants have relied on Psychemedics to determine that the Hair Test is accurate and reliable, they have also purported to rely on Dr. Thomas Mieczkowski of the University of South Florida. Specifically, a copy of a document called "Hair Drug Testing: Fact vs. Fiction" that BPD Labor Relations employees Sandra DeBow and Alicia McDonnell prepared for publication on the BPD's internal website is attached hereto as ***Exhibit 4***. Question 4 asks "Can I test positive from external or environmental contamination or exposure to drugs?" The response relies on one of Dr. Mieczkowski's studies at the University of South Florida:

No. There are two different ways that an individual could potentially have a positive drug test from external or environmental contamination:

- 1) from passive inhalation (inhaling marijuana or crack smoke that is smoked by someone else), or
- 2) by having the drug on the outside of your hair, (handling cocaine and then touching your hair).

The Psychemedics tests address both these potential problems.

For external contamination, (having drugs on your hair) Psychemedics has an elaborate "washing" process, which includes washing the hair sample multiple times and testing the wash water for the presence of drugs before any testing on the hair sample begins.

A recent study by the University of South Florida of police officers in the Narcotics Unit of the Miami/Dade County Police Department illustrates this process well. It found that although each narcotics officer's hair was externally contaminated with cocaine, as shown through the hair washing process, none of the officers had positive test result for cocaine or any other illegal narcotic. This holds true for our Department as well, as no police officer in either the Drug Control Division or the Youth Violence Strike Force has tested positive for drugs.

For passive inhalation concerns, the cutoff levels used by Psychemedics are set high enough to prevent problems with passive inhalation. To test above a cutoff level, the donor must have engaged in repeated drug use prior to the hair collection date. One time exposure will not result in a positive drug test.

In addition to the Hair Test Q&A document, BPD Sergeant Detective Joseph T. Devlin prepared an interoffice memorandum for BPD Commissioner James M. Hussey concerning the American Association of Medical Review Officers ("AAMRO") 2003 Drug Testing Symposium.

A copy of the memorandum is attached hereto as ***Exhibit 5***. When it came to “racial bias in hair testing,” a subject discussed at the AAMRO conference by Dr. Yale H. Caplan, Director of National Scientific Services, Mr. Devlin concluded that “Dr. Caplan presented a very misleading and factually erroneous presentation to an entire room full of Medical Review Officers. . . Dr. Caplan’s presentation nurtured the belief that hair testing is potentially racially biased while presenting evidence that clearly shows no such thing and at most suggested a potential only for ‘hair color bias.’” Mr. Devlin concluded that the “judgment” of Dr. Caplan and another “presenter, Dr. Edward J. Cone,” was “affect[ed]” by “their individual biases” because they “currently work for (or own) private laboratories or consulting firms that have a vested interest in promoting one type of testing over another.” Instead of these scientists, Mr. Devlin pointed to the work of “Dr. Thomas Mieczkowski” who “was not at the conference.” Mr. Devlin thought his superiors should rely on Dr. Mieczkowski’s independence over Drs. Caplan and Cone:

Dr. Mieczkowski is a professor in the Department of Criminology at the University of South Florida. Unlike those presenters who previously or currently work for laboratories and/or consulting firms, Dr. Mieczkowski is a professor and researcher who has analyzed past studies conducted on hair drug testing as well as having conducted studies of his own (see attached copies of studies and/or abstracts). His findings conclude that any evidence of racial or hair color bias is either statistically insignificant or is no greater than statistical variances that exist within racial or ethnic groups. Lending further credence to the results of his research, Dr. Mieczkowski has conducted several large scale studies (one of which included over 56,000 subjects) instead of the poorly designed, small scale studies that are frequently cited by others to discredit the reliability of hair testing.

As it turns out, Dr. Mieczkowski’s research has been bought and paid for by Psychemedics. Dr. Mieczkowski’s University of South Florida website has a link to his Curriculum Vitae as of October 31, 2003. A copy of Dr. Mieczkowski’s publicly available CV is attached hereto as ***Exhibit 6***. The CV is also available at http://web3.cas.usf.edu/main/depts/CCJ/faculty/data/tmieczkowski_cv.pdf. According to this outdated CV, which lists Dr. Mieczkowski’s “Grants And Contracts” through 2001, Dr. Mieczkowski had received the following grants from Psychemedics:

- A \$2,000 “Travel Grant” in 1991 for a “Presentation to the International Association of Forensice Toxicology, Genoa, Italy.”
- A \$2,000 “Travel Grant” in 1993 for a “Presentation to the International Association of Forensice Toxicology, Genoa, Italy.”
- A \$2,000 “Travel Grant in 1995 for a “Presentation to the International Association of Forensice Toxicology, Genoa, Italy.”
- A \$10,000 “Travel Grant in 1999 for a “Presentation to the International Association of Forensice Toxicology, Martingy, Switzerland.”
- A \$38,000 “Sabbatical Research Fellowship” in 2000-2001.⁴

One of the Genoa, Italy presentations that Psychemedics paid Dr. Mieczkowski to give was called “Distinguishing Passive Contamination from Active Cocaine Consumption: Assessing the Occupational Exposure of Narcotics Officers to Cocaine.” This paper is attached hereto as ***Exhibit 7***. This is also the paper defendants cited in the Q&A, and it is one of the small handful of scientific articles concerning hair testing that defendants have produced in discovery.

During his deposition, Mr. Devlin was asked about his 2003 memorandum concerning the AAMRO convention and the “independence” of Dr. Mieczkowski’s work. He was then asked about Psychemedics’s payments to Dr. Mieczkowski as reflected on his publicly available CV. Pertinent portions of Mr. Devlin’s testimony are attached hereto as ***Exhibit 8***. Mr. Devlin testified that he did not know about the grants, and, if he had known, he probably would not have described Dr. Mieczkowski as independent in his memorandum to Commissioner Hussey. Devlin Transcript at 100:21-101:7.

Requests 11-14 seek documents that are highly relevant to this litigation because they concern whether the studies defendants will use to bolster their position that the Hair Test is reliable were performed by scientists who are truly independent from Psychemedics. The limited

⁴ Dr. Mieczkowski is also the editor of the *International Journal of Drug Testing*. Thomas Cairns of Psychemedics is on the Editorial Board of the *International Journal of Drug Testing*. So is Dr. Carl Selavka, who resigned as civilian director of the Massachusetts State Police crime laboratory on March 12, 2007 “over the alleged mishandling of DNA test results in about two-dozen unsolved sexual assault cases.” See Jonathan Saltzman, *Director of crime lab quits post: State Police facility’s work is under fire*, Boston Globe, March 10, 2007. The defendants have called Dr. Selavka as an expert witness in several arbitrations to defend the validity of the Hair Test.

publicly available information concerning Dr. Mieczkowski was sufficient to change the mind of one BPD employee concerning the independence of Dr. Mieczkowski. Plaintiffs must have all responsive documents to explore this issue beyond the tip of the iceberg. Therefore, plaintiffs request that the Court order Psychemedics to produce all documents responsive to requests 11-14.

F. Requests 15-17 and 26: Documents And Communications Concerning Psychemedics's Status as a Licensed And Certified Laboratory

Request 15 seeks: "All documents and communications concerning Psychemedics's compliance with 21 CFR Part 809.40(c), which requires that a laboratory testing hair for drugs of abuse "shall have, and shall be recognized as having, adequate capability to reliably perform the necessary screening and confirmatory tests, including adequate capability to perform integrity checks of the biological specimens for possible adulteration."

Request 16 seeks: "All documents and communications concerning Psychemedics's certification in the area of toxicology by the Health Care Financing Administration, the College of American Pathologists, or any other organization with deemed status in the area of toxicology."

Request 17 seeks "All documents and communications concerning Psychemedics's status as a licensed laboratory certified to perform hair testing. This request includes, but is not limited to, Psychemedics's Clinical Laboratory Improvement Amendments of 1998 (CLIA) Application for Certification."

Request 26 seeks: "All documents and communications concerning Psychemedics's status as a certified laboratory to perform hair testing as described in Rule 111, Appendix D of Defendants' Substance Abuse Policy."

In the meet-and-confer, Psychemedics's counsel agreed to produce all of Psychemedics's licenses and certifications in response to Requests 15-17 and 26. Except for certain documents attached to an affidavit filed in opposition to the Motion to Compel SOPs, Psychemedics has not produced its licenses and certifications. These documents are relevant to this litigation, because,

on information and belief, Psychemedics is not “a licensed laboratory that is certified to perform hair testing” as required by Appendix D, Part I of BPD Rule 111 (attached to the subpoena, which is attached as *Exhibit A* to the Motion to Compel SOPs). Therefore, plaintiffs request that the Court order Psychemedics to produce its license and certifications.

G. Requests 21: “All documents concerning Psychemedics’s participation in any study sponsored or administered by the Society For Hair Testing, the Substance Abuse and Mental Health Services Administration, or RTI International, including, but not limited to, the results of any such study.”

During the meet-and-confer, Psychemedics’s counsel stated that he did not think Psychemedics had participated in any studies that are relevant to this litigation. In response, plaintiffs’ counsel described their understanding that Psychemedics participated in at least one study by SAMHSA and/or the Research Triangle Institute (“RTI”) concerning the effectiveness of wash procedures in addressing the external contamination of hair samples. Despite representing that he would follow-up with Psychemedics regarding what documents are available that are responsive to this request, Psychemedics’s counsel never provided a response to plaintiffs’ counsel concerning this request (or any other request).

A copy of an article concerning the RTI study that was published in the October 2006 *Journal of Analytical Toxicology* is attached hereto as *Exhibit 9*. The study addressed whether wash procedures could be used to eliminate external contamination as the cause of a positive hair test result. The requested documents are relevant to this case because they concern how Psychemedics’s hair test performed in an independent government funded study. According to the journal article,

In 2000, RTI International was directed by the Division of Workplace Program, Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS), to conduct a pilot hair performance testing (PT) under the National Laboratory Certification Program (NLCP). The purpose of this pilot was to develop quality assurance testing materials in support of anticipated changes in Federal Drug-Free Workplace testing programs.

Exhibit 9 at page 490. According to the article, “Three commercial analytical laboratories analyzed samples under three protocols: no decontamination procedure, individual laboratory decontamination, or decontamination by an extend buffer procedure at RTI International.” *Id.* The article does not state whether Psychemedics was one of the laboratories that participated in the study; however, Mr. Thistle’s statements from the minutes of a December 12, 1006 Drug Testing Advisory Board meeting reflect that Psychemedics was one of the labs that participated in the RTI study. Pertinent portions of the December 12, 2006 Drug Testing Advisory Board minutes are attached hereto as **Exhibit 10**.

The RTI study made several statements, findings, and conclusions that are significant to this litigation:

- “Testing for drugs in hair has evolved to the point that the identity of the drug found is less of an issue than the explanation of its origin. The risk for environmental contamination alone to produce a positive drug hair test result is not clear.” **Exhibit 9** at page 490.
- “All mechanisms by which drug is incorporated into hair are not fully understood. Drug incorporation into hair can occur through blood exchange at the hair follicle; exposure to sweat and sebaceous secretions; transdermal diffusion of drug from the skin; and also from exposure to the external environment, including drug residues, contaminated surfaces, and vaporized drug. Each of these mechanisms is affected by the chemical and physiological composition of the hair matrix.” *Id.* at 490-91.
- “The extent to which hair can be decontaminated depends on factors governing penetration of the drug into the hair matrix such as cosmetic treatment of hair and the chemical and physical properties of the drug analyte.” *Id.* at 491.
- “Hair decontaminated at the analytical laboratories contained significantly more COC, BE, and CE than hair decontaminated at RTI until approximately day 21 of the study period.” *Id.* at 495.
- “The application of the proposed Federal Mandatory Guideline criteria for designating a hair specimen as positive or negative to the data obtained in this study are presented in Table III. When the proposed criteria . . . were used to designate an analytical result as positive, 235 of 585 total analytical results for the contaminated hair aliquots would have been called positive, including those samples that had no decontamination performed. **Of the 390 samples that were decontaminated, 148 samples still met the proposed criteria to be called positive. For all hair types, there were samples that would have been called positive by at least one analytical laboratory for almost the entire period.**” *Id.* at 497 (emphasis added).

- “Hair is a dynamic material of which water is an integral part. In light of the results obtained for the hair samples before they were wet with artificial sweat, it is possible that changes in humidity throughout shipping and storage aided the migration of COC from the surface into the hair matrix with the resulting incorporation being resistant to removal. **This phenomenon merits further study and, if confirmed, would further confound discriminating drug positives due to ingestion from those due to environmental contamination.**” *Id.* at 498 (emphasis added).

Thus, a government funded study concluded that 38% of hair samples from non drug users tested positive when their hair was externally contaminated, even after the hair was decontaminated by wash procedures used by Psychemedics and two other hair testing laboratories. Such a high percentage of false positives makes hair testing arbitrary, and, therefore, plaintiffs have demonstrated a compelling need to know exactly how poorly Psychemedics’s wash procedures performed in this independent study. Plaintiffs request that the Court order Psychemedics to produce all documents responsive to Request 21.

H. Request 23: Samples of Hair Specimens taken from each of the Plaintiffs sufficient in size to allow for independent DNA testing by another laboratory to be performed on the samples produced.

Psychemedics previously agreed to produce the individual plaintiffs’ hair samples after the plaintiffs and defendants agreed to some procedure for dealing with these samples since they would likely be destroyed by DNA testing. During the meet-and-confer, plaintiffs’ counsel agreed that this was a reasonable approach, and Psychemedics’s counsel agreed to inform the plaintiffs regarding how much of their hair samples remain in Psychemedics’s control. Months after this agreement, Psychemedics has not confirmed whether it would be able to produce the individual plaintiffs’ hair samples in quantities sufficient to permit DNA testing. Therefore, plaintiffs seek an order compelling Psychemedics to confirm whether it still has any of the individual plaintiffs’ hair samples that were used as part of the Hair Test.

I. Requests 29 and 30: Documents Concerning Psychemedics’s Cut-Off Levels For The Hair Test.

Requests 29 seeks: “All documents and communications concerning the cut-off levels for cocaine for the initial hair test. The time period for this request is January 1, 1994 to the present.”

Request 30 seeks: “All documents and communications concerning the determination of and any changes made to the cut-off levels for cocaine applicable to the Hair Test, including the Safety Net Test, where “cut-off levels” means the value at which a result of the Hair Test is reported as positive for the presence of illegal drugs and below which a result is reported as negative for the presence of illegal drugs. The time period for this request is January 1, 1994 to the present.”

During the meet-and-confer, Psychemedics’s counsel agreed to produce documents that it had already provided to the defendants, which were responsive to these requests. Psychemedics has still not produced any documents. After the BPD began using the Hair Test in 1999, it lowered the cut-off level for the Safety Net Test. To the extent Psychemedics communicated with the defendants concerning its decision to lower the cut-off level, these documents are relevant to this case because plaintiffs are challenging the Hair Test’s cut-off levels as inadequate in discerning ingestion of cocaine from external contamination. Therefore, plaintiffs seek an order compelling Psychemedics to produce documents that it provided to the defendants that are responsive to Request 29 and 30.

J. Requests 31-32 and 39-40: Documents Concerning The Hair Test’s Racial Bias And The Impact of External Contamination.

Request 31 seeks: “All documents and communications concerning whether Psychemedics’s Hair Testing has a racial, hair texture, or hair color bias, including documents and communications concerning whether the likelihood of a positive test result is correlated with a person’s race, hair texture, or hair color.”

Request 32 seeks: “All documents and communications concerning whether Psychemedics’s Hair Testing is affected by a person’s passive exposure to drugs of abuse, including cocaine.”

Request 39 seeks: “All documents and communications concerning whether contamination, passive exposure, bias of any kind, sample handling, record keeping, interpretation, or any other factors or phenomena do affect or might affect the results of

Psychemedics's Hair Testing or the accurate, objective, neutral, and unbiased reporting Psychemedics's Hair Testing results, including all documents and communications concerning any presentation, discussion, analysis, assessment, or evaluation of potential or actual bias or disparate impact, based upon race or any other factor, related to Psychemedics's Hair Testing and all documents and communications concerning any discussion, analysis, assessment, or evaluation of alternative drug testing methods with less potential or actual bias or disparate impact that that associated with or related to Psychemedics's Hair Testing."

Request 40 seeks: "All documents and communications concerning the accuracy and reliability – or lack thereof – of all aspects of Psychemedics's Hair Testing, including the standards, methods, procedures, and criteria to be applied in the collection, transmission, storage, and testing of the samples; the analysis interpretations, confirmation, and reporting of the test results; and the retention of samples and records after Psychemedics's Hair Testing results are reported to the Defendants."

During the meet-and-confer, Psychemedics's counsel agreed to produce any studies it had that are responsive to these requests. Psychemedics's counsel also stated that it would be a huge burden on Psychemedics to try and collect every document sent to Psychemedics concerning these issues. Plaintiffs' counsel inquired as to how difficult it would be to produce any responsive documents drafted by Psychemedics, as well as any documents Psychemedics has already collected in a file (e.g., a file of documents concerning hair color or race bias issues). Psychemedics's counsel agreed to inquire with Psychemedics whether to agree to produce documents responsive to these narrower criteria. In addition to these narrower criteria, plaintiffs' counsel stated in the April 13, 2007 letter that plaintiffs would need any documents concerning discussions on the design of responsive studies (published or unpublished) and all published and unpublished results of such studies. Psychemedics never produced any documents in response to these requests and never responded to plaintiffs' counsel concerning the narrower criteria.

Documents concerning the Hair Test's racial bias and external contamination are at the core of every allegation in the Amended Complaint. Therefore, plaintiffs request that the Court order Psychemedics to produce all documents responsive to Requests 31, 32, 39 and 40.

K. Requests 33 and 37-38: Documents Concerning False Positives And Psychemedics's Collection of Hair Color, Hair Texture, And Race Data in Connection With Its Hair Test.

Request 38 seeks: "All documents and communications concerning any instance in which a Hair Test reported as positive for one or more illegal drugs was deemed to be erroneous or inconclusive as to the question whether the person had actually ingested any illegal drug, including cocaine."

Request 33 seeks: "All documents concerning Psychemedics's procedures for determining the color of a hair sample, including, but not limited to, Psychemedics's procedures for determining the natural hair color of a hair sample."

Request 37 seeks: "All documents concerning the race, hair texture, hair color, and test result of persons who Psychemedics tested for drugs, including cocaine."

During the meet-and-confer, Psychemedics's counsel represented that Psychemedics does record the hair color (although not necessarily the natural hair color) and texture of all hair samples for chain of custody reasons. However, Psychemedics does not collect aggregate hair color and texture data in any database. Plaintiffs' counsel agreed to withdraw Request 33 if Psychemedics would confirm these representations in writing. Similarly, during the meet-and-confer, Psychemedics's counsel represented that Psychemedics does not collect responsive data concerning the race of its test subjects. Once again, plaintiffs agreed to withdraw Request 37 if Psychemedics would confirm its counsel's oral representation in writing. Finally, during the meet-and-confer, Psychemedics's counsel represented that there are no documents responsive to request 38. Psychemedics never confirmed any of these representations in writing. Therefore, plaintiffs request that the Court order Psychemedics to confirm in writing that it does not collect

aggregate data concerning hair color, hair texture, and race for those individuals it has conducted the Hair Test and does not have any documents responsive to Request 38.

L. Requests 41: “All documents and communications concerning complaints, grievances, petitions, or lawsuits concerning the Hair Test, hair drug testing in general, or Psychemedics’s Hair Testing.”

During the meet-and-confer, Psychemedics’s counsel represented that grievances are “constantly” brought against Psychemedics, so Psychemedics would not produce any documents responsive to Request 41 unless plaintiffs could narrow this request. Psychemedics’s counsel also represented that Psychemedics does not formally track its grievances. Psychemedics’s counsel also said he was relatively certain that Psychemedics does not track complaints concerning hair color or race bias. Plaintiffs’ counsel asked Psychemedics’s counsel to confirm whether and how Psychemedics formally tracks complaints against it. Psychemedics’s counsel never responded regarding this or any other issue addressed during the meet-and-confer. These documents are relevant because the defendants and Psychemedics have stated many times that the hair test has been “upheld by the courts” without elaborating on precisely what that means. Therefore, plaintiffs seek an Order compelling Psychemedics to produce all documents responsive to Request 41.

CONCLUSION

For all the foregoing reasons, the Court should grant this motion and issue an order compelling Psychemedics to comply with its discovery obligations under the Federal Rules of Civil Procedure by immediately producing the documents described above and in the form of proposed Order submitted as *Exhibit A* to the accompanying Motion. Further, Psychemedics should be ordered to pay the plaintiffs’ costs, including attorneys’ fees, incurred in bringing this Motion, in an amount to be determined upon submission of an affidavit setting forth such costs.

Respectfully submitted,

Ronnie Jones, Richard Beckers, Walter Washington, William Earl Bridgeforth, Shawn

**N. Harris, Eugene Wade George C. Downing,
Jr., Clararise Bristow, and the Massachusetts
Association of Minority Law Enforcement
Officers,**

By their attorneys,

/s/ Robert B. Baker

Louis A. Rodriques, BBO # 424720

Rheba Rutkowski, BBO # 632799

Raquel J. Webster, BBO # 658796

Robert B. Baker, BBO # 654023

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Lawyers' Committee for Civil Rights

Under Law of the Boston Bar Association

294 Washington Street, Suite 443

Boston, Massachusetts 02108

Marcia Woodham, BBO # 600886

SABEL & SABEL, P.C.

Hillwood Office Center

2800 Zelda Road; Ste. 100-5

Montgomery, AL 36106

Dated August 17, 2007

CERTIFICATE OF SERVICE

I hereby certify that, on August 17, 2007, a true copy of the above document was served upon the attorney of record for each other party by first class mail and electronically via the ECF/CM. In addition, I hereby certify that, on August 17, 2007, a true copy of the above document was served upon counsel for Psychemedics, J. Allen Holland, Jr., by U.S Mail and via ECF/CM.

/s/ Robert B. Baker

Exhibit 1

BINGHAM

LEGAL INSIGHT. BUSINESS INSTINCT.

Robert B. Baker
 Direct Phone: (617) 951-8873

May 31, 2007

Via U.S. Mail and Facsimile

J. Allen Holland, Jr.
 Lynch, Brewer, Hoffman & Fink, LLP
 101 Federal Street, 22nd Floor
 Boston, MA 02110-1800
 Facsimile: (617) 951-0811

**Re: Jones, et al. v. City of Boston, et al., Case Number 05-11832:
 Subpoena to Psychemedics Corporation ("Psychemedics")**

Dear Mr. Holland:

I write to follow-up concerning the meet-and-confer telephone call we had on April 11, 2007 and the letter I sent you regarding that telephone call on April 13, 2007. During the conference call, you stated that Psychemedics would agree to produce documents in response to several of plaintiffs' document requests. You also stated that you would have further conversations with Psychemedics to see if other document requests could be resolved short of a motion to compel. You called me on April 13th to say that you and Psychemedics would need additional time to address these issues, but, even with the additional time, I expected to receive by the end of April both a document production and Psychemedics's final position on the issues taken under advisement.

It is now the end of May and I have heard nothing from you in response to our April 11th meet-and-confer, and Psychemedics has not produced a single document in response to plaintiffs' November 3, 2006 subpoena. While the plaintiffs have a strong interest in resolving these issues without court intervention, their patience is not limitless. I therefore request that you inform me of the status of Psychemedics's document production by June 4, 2007 in order to avoid motion practice on all of the outstanding issues referenced in my April 13th letter.

Very truly yours,

Robert B. Baker

Enclosure

cc: Rheba Rutkowski, Esq.
 Raquel Webster, Esq.
 Eric Heinig, Esq.

Bingham McCutchen LLP
 150 Federal Street
 Boston, MA 02110-1726

T 617.951.8000
 F 617.951.8736
 bingham.com

JOB STATUS REPORT

TIME : 05/31/2007 16:28
NAME : BINGHAM MCCUTCHEN LP
FAX# : 1
TEL# : 1
SER.# : BR04J2525664

DATE, TIME	05/31 16:28
FAX NO./NAME	96179510811
DURATION	00:00:27
PAGE(S)	02
RESULT	COVER SHEET
MODE	OK
	STANDARD
	ECM

Facsimile

DATE: May 31, 2007

	NAME	FAX	PHONE
Bingham McCutchen LLP 150 Federal Street Boston, MA 02110-1726	TO: J. Allen Holland, Jr. Lynch, Brewer, Hoffman & Fink, LLP	617-951-0811	
617.951.8000 617.951.8736 fax	FROM: Robert B. Baker robert.baker@bingham.com	(617) 951-8736	(617) 951-8873
bingham.com	PAGES: (INCLUDING THIS COVER PAGE): 2		
Boston Hartford London Los Angeles New York Orange County San Francisco Silicon Valley Tokyo Walnut Creek Washington	RE: Jones, et al. v. City of Boston, et al. Case Number 05-11832		
MESSAGE:			

For transmission problems, please call (617) 951-8925

The information in this transmittal (including attachments, if any) is privileged and confidential and is intended only for the recipient(s) listed above. If you are neither the intended recipient(s) nor a person responsible for the delivery of this transmittal to the intended recipient(s), you are hereby notified that any unauthorized reading, distribution, copying or disclosure of this transmittal is prohibited. If you have received this transmittal in error, please notify us immediately at (same telephone number as in first paragraph - will duplicate) and return the transmittal to the sender. Thank you.

Timekeeper No:	13800	Client/Matter No:	999997/928537	DATE/TIME STAMP
Client/Matter Name:				
Return To:	Robert Baker		Floor No:	17

Exhibit 2

MEMORANDUM

To: File
From: Robert Boyle
Date: July 8, 1999

Sandra DeBow arranged a meeting at BPD HQ. Patrick Kelley from Psychemedics in Atlanta made a presentation. Bill Thistle (hereinafter "BT") from Psychemedics in Cambridge attended and answered questions. Several BPD members were present: Bobby Mullan, Bernie Kelly (hereinafter "BK") and Michael Sullivan from BPD's EAP, Sup. James Hussey and Joseph Devlin.

Patrick Kelley showed a Psychemedics videotape on sample collection procedures. It was the same videotape that the City provided the BPPA during negotiations over implementation of hair testing in Rule 111. After the videotape, Kelley explained how drugs get into hair. Kelley started to talk about fingernails and pubic hair when BT explained that BPD does not use either.

Patrick Kelley discussed the possibility of prescription drugs contributing to a positive test result. He said that while there is Tylenol with Codeine, no doctor would prescribe the amount of medication necessary to score positive. A positive test would only result from uncontrolled levels of Codeine. Kelley said that cancer patients taking some THC-based prescription medications may return positive for Marijuana. A Morphine positive may also be based upon a prescription, such as if there was a recent physical injury. Kelley said that the MRO would be able to sort through all of these. He said that there is no prescription for Cocaine or Heroin.

The two BPD officers from EAP asked questions about the hair testing process.

BT said that the plastic pouch for hair samples is opened at the bottom. If a subject claims tampering with the seal, Psychemedics can provide a Xerox copy of the intact sealed bag.

BT recommended a mirror at the collection site. (Outside the meeting, Bobbie Mullan said that BPD does not provide a mirror. She is waiting for direction from Labor Relations)

BK asked why the sample collectors do not wear gloves. BT said that Psychemedics provides gloves to sample collectors, but the gloves are for the convenience of the sample collector, not because of any concern that bare hands could contaminate a hair sample.

BK then asked BT if external contamination was a concern. BT said that external exposure to drugs can lead to drugs getting into the bloodstream, but in such small amounts that the appropriate cut-off level would render it a negative. BT said that the

cut-off levels are high enough to eliminate passive ingestion and even low level use of drugs.

BK asked if marriage to a drug-user puts an officer at risk for a positive result. This led to a discussion of a challenge to a positive hair test based upon the subject's claim that sexual relations (i.e., oral sex) with a drug user caused the positive result. BT said the evidence in that case was that the drug levels in semen are very low.

Sandra DeBow asked BT to discuss a study on hair testing of narcotics officers. BT explained that the study of narcotics officers showed that external contamination was not an issue.

BK asked if Psychemedics has had any court challenges. BT went back to talk about the sexual transmission challenge. He said the subject claimed that her positive test was due to sexual transmission, use of Fen-Fen, and external contamination from removing a Methamphetamine lab from her mother-in-law's house.

BK then asked if about prescription medications: do any antidepressants have the ability to make a test come back positive? BT said that there are drugs that screen the same as some antidepressants (RIAH screen) but the second test (GCMS) gives a molecular fingerprint of each drug, and they can be distinguished.

BK asked if there is anything to the racial bias claim. BT gave the explanation that the studies raising the concern use only a handful of subjects. The best studies, he said, involve thousands of subjects. Those studies all show the absence of a hair bias. In these studies, the results of hair testing, urinalysis and self-reporting are compared for different racial groupings. He said the differences across racial lines are proportionate.

BT explained that while Cocaine binds with Melanin, it also binds with other proteins in hair. He said Melanin makes up only a small percentage of the total weight of a strand of hair.

BT went on to say that a preference among blacks for Cocaine also explains the higher rate of positives for that group. He said that cocaine is the "drug of choice" for blacks whereas Methamphetamine is the "drug of choice" for whites. He said that Methamphetamine is a "Caucasoid", meaning, it is a drug that Caucasians use.

BT said that the race bias claim was baseless but that the media likes controversy so it continues to stir the pot.

BT said that Psychemedics's clients keep records of the rate of positives and also the demographics among those who test positive.

BK asked about other firms that are available to do hair testing. BK said that people he sees at EAP want independent tests. BT said that there are other labs, some whose work

is better than others. He said that any hair testing lab needs the right equipment. BT said that in court employers challenge the other lab's chain of custody.

BK asked about Safety Net Tests. He said that on occasion Psychomedics has responded that there was insufficient hair in the sample. The lab tested for everything but Cocaine first when the first test was only positive for Cocaine. BT said he would inquire to see "what went . . . with that test" (i.e., what went wrong, but he didn't say "wrong"). BK said that the Department has had negative Safety Net Tests. What bothers him is a Safety Net Test that comes back as a bad sample (i.e., no answer).

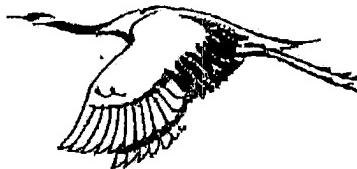
BK said that people at EAP are screaming and crying. They are extremely upset that they tested positive. Sup. Hussey asked how far back do fingernail samples test. BT said 6 to 8 months ago (i.e., the tip of your fingernail is 6 to 8 months old). The newest part of a fingernail is at the base. Scrapings of fingernails can test for drug use in the past 3 months. Sup. Hussey said that he wants to be able to tell officers reporting to EAP what they can do to try to prove their innocence. BT said that people do use negative re-tests as a defense, but that the negative retest only shows that the person is not a habitual user. It does not show that the person "never used drugs" and it doesn't refute the original test.

Michael Sullivan asked how many false positives Psychomedics has had. BT said there has never been a reported false positive in Psychomedics ten years of testing. He said that no one who has ever claimed to have received a false positive was ever proven to be right. Sullivan asked if Psychomedics could provide a chart showing the cut-off levels that the lab uses to define positive results for the different drugs tested. Sullivan also asked if officers ordered to EAP could obtain access to Psychomedics test results data (i.e., regarding other subjects).

After the meeting, Bobbie Mullan told BT that the Department has had two negative Safety Net Tests.

After the meeting, Patrick Kelley provided hair sample collection training to four BFD personnel in Bobbie Mullan's office. They did not review the videotape but watched as Kelley demonstrated hair collection technique.

Exhibit 3



TO: Ray Kubacki

FAX: 617 864-1639

FROM: Bob Stephenson

DATE: April 4, 2002

P. S. I'll call tomorrow.

NUMBER OF PAGES (including cover sheet): 3

RE: Here are 2 pages from the
Current draft of the Guideline
revisions. You will see that the
cutoffs are exactly as requested by the industry
working group - who ever shared the
copy with different information shared a document
in process DIVISION OF WORKPLACE PROGRAMS
not ever released.

Bob S.

CSAP/SAMHSA/HHS

5600 FISHERS LANE, ROCKWALL 2 BLDG., ROOM 815

ROCKVILLE, MARYLAND 20857

PHONE: 301-443-6780 (MAIN NUMBER)

AND 301-443-6014 (DRUG TESTING)

OFFICE FAX: 301-443-3031

Exhibit 4

Hair Drug Testing: Fact vs. Fiction

Since the introduction of hair drug testing in January of 1999, the Department has conducted over 6,804 hair tests on samples provided by police officers. Only forty-five officers have tested positive in that time, out of the approximately 2,200 sworn officers who have been tested annually. That is less than 2% of all officers: a rate below the national average. However, since the Department continues to get questions about hair testing, you'll find a brief list of the most frequently asked questions about the Department's drug-testing procedures and policies listed for your reference below.

Background:

Together the unions and the Department share a joint desire to achieve and maintain a work force that is 100% drug-free. The sworn unions and the Department agreed to reach this goal through fair, reasonable, and objective testing procedures. During negotiations, the Department proposed an annual hair drug test in response to the Boston Police Patrolmen's Association's (B.P.P.A.) opposition to random urine testing. Hair testing can detect drug use for a longer time period, is harder to adulterate, and is less invasive than urine testing. Both the Department and the union had an opportunity to examine and discuss various issues, such as the scientific validity of the testing methods, time frames for drug detection and the concerns for bias or inaccurate test results. In July 1998, the Department reached agreement with the B.P.P.A and the annual hair test was added to the collective bargaining agreement. The other sworn unions negotiated the annual hair test, which ultimately became a part of their contracts through subsequent interest arbitration awards.

1. Why does the Department use Psychomedics' laboratory to conduct hair tests?

Psychomedics is the premier hair testing laboratory for hair tests of employees. It conducts more hair tests than any other laboratory in the world. The Psychomedics laboratory is the only lab in the United States to be approved by the FDA to conduct hair analysis drug testing for the five illicit drugs that we test for under Rule 111 (Cocaine, Methamphetamine, Opiates, PCP and Marijuana).

Psychomedics conducts hair testing for over 1,600 Fortune 500 companies and numerous major metropolitan police departments including: New York City, Chicago, Philadelphia, Minneapolis, San Francisco and Las Vegas.

Psychomedics has conducted well over two million hair drug tests. Because it conducts so many hair tests, Psychomedics' procedures and technology have been heavily challenged and have consistently been upheld in every court in which they have been challenged. Furthermore, every arbitration case the Department has defended has found the testing to be a fair, reasonable, and objective hair analysis test. For copies of the arbitration decisions regarding

drug testing, please contact Alicia McDonnell in the Legal Advisor's Office at 343-5037. For more information about Psychemedics' laboratory, visit www.psychemedics.com

2. What is the process used for testing hair for drugs?

Collection: The Department personnel that collect the hair samples are specially trained to follow a specific protocol to collect a sufficient quantity of hair to be tested at Psychemedics. The protocol has stringent chain-of-custody procedures, and the hair collectors have been well trained on how much hair is needed, and the specific areas from which the hair should be collected (head, nape of neck, face, etc.). The officer having his/her hair collected cannot dictate the amount of hair collected, or the collection location. (See Rule 111, Appendix D for collection, testing and reporting procedures.).

Note: The medical staff personnel who collect the hair samples do so professionally and diligently. They do not have the authority to deviate from the collection protocols. Further, they are not there to debate the hair collecting process or the testing methodology. Failure to submit to an annual hair test under the procedures dictated by the medical staff may be considered a refusal to be tested and will result in appropriate discipline. Officers who have questions or concerns about their collection should not address them to the medical staff but to their union or the Bureau of Internal Investigations.

Testing: Once Psychemedics receives the hair sample, the chain-of-custody is confirmed. Then, the sample is decontaminated through a multi-stage washing process. The hair sample is then divided into several smaller hair samples to allow for screening and confirmation testing. The first portion of the sample is digested into a liquid state. The digested sample is then subjected to a Radioimmunoassay (RIA) test, which is a screen test to detect the presence of the five drugs.

If the RIA test indicates the presence of one or more drugs, another portion of the hair sample is then digested and subjected to a more accurate test, Liquid Chromatography Mass Spectrometry Mass Spectrometry (LC/MS/MS) or GC/MS, which confirms the presence of the drug screened by the RIA.

If the LC/MS/MS or GC/MS test results indicate the presence of a drug above the cut-off level, the test is deemed positive and Psychemedics forwards the test results to the Medical Review Officer (MRO). (See Rule 111, Appendix D, Section J). To learn more about hair drug testing, visit: www.drugtestwithhair.com.

Cutoff levels. All drugs are screened at a specific cutoff level. The cutoff level is established by the laboratory and industry standards, and ensures that low levels of drugs from external or passive contamination will not result in a positive drug test. The cutoff levels are different for each drug and for each type

of scientific test, e.g., the RIA versus LC/MS/MS or GC/MS.

3. What/Who is a MRO?

The Medical Review Officer (MRO) is an independent doctor who reviews all positive drug test results. An MRO is a licensed physician who has knowledge of substance abuse disorders and medical training to interpret and evaluate a positive test result relative to the donor's medical history.

After the laboratory conducts a drug test that is positive, it sends the results directly to the MRO, not the Department. The MRO then reaches out to the donor and asks about any alternative medical explanation for the positive drug test result.

If the donor has a valid, medical reason for the presence of drugs in his/her system, e.g., a valid prescription drug, then the positive result is reported as a negative to the Department. If the donor does not have a legitimate alternative medical reason, the test is reported as positive (See Rule 111, Appendix D for more detailed information).

4. Can I test positive from external or environmental contamination or exposure to drugs?

No. There are two different ways that an individual could potentially have a positive drug test from external or environmental contamination:

- 1) from passive inhalation (inhaling marijuana or crack smoke that is smoked by someone else), or
- 2) by having the drug on the outside of your hair, (handling cocaine and then touching your hair).

The Psychededics tests address both these potential problems.

For external contamination, (having drugs on your hair) Psychededics has an elaborate "washing" process, which includes washing the hair sample multiple times and testing the wash water for the presence of drugs before any testing on the hair sample begins.

A recent study by the University of South Florida of police officers in the Narcotics Unit of the Miami/Dade County Police Department illustrates this process well. It found that although each narcotics officer's hair was *externally contaminated* with cocaine, as shown through the hair washing process, *none* of the officers had positive test result for cocaine or any other illegal narcotic. This holds true for our Department as well, as no police officer in either the Drug Control Division or the Youth Violence Strike Force has tested positive for drugs.

For passive inhalation concerns, the cutoff levels used by Psychededics are set high enough to prevent problems with passive inhalation. To test above a

cutoff level, the donor must have engaged in repeated drug use prior to the hair collection date. One time exposure will not result in a positive drug test.

5. Is there a race bias in hair testing?

No. There is a misguided theory that race is a factor in drug testing results, and that it could possibly cause a positive drug test result. This theory is scientifically invalid, and has mis-characterized the original theory regarding hair color.

A few scientifically flawed, early studies proposed that dark hair (not specific to any particular race) has more melanin than lighter hair. This rate of melanin was thought to have resulted in longer detection times. Therefore, it was argued, individuals with dark hair would test positive more frequently than those with lighter hair because the drug stays in the hair longer.

This hair color theory never suggested that melanin *caused* positive drug tests. Rather, the theory suggested that drugs that had been *ingested* would remain in dark hair longer than those with lighter hair color.

Subsequently, this hair color theory has been repeatedly and categorically disproved by large-scale, scientifically valid studies. Hair color or the amounts of melanin present have both been shown to have no effect on the outcome of a drug test. Copies of these studies are available in the Office of the Legal Advisor at Headquarters by calling Alicia McDonnell at 343-5037.

6. If I am taking prescription medications, will I test positive for illegal drugs?

On the "test request form" that is used during the sample collection there is a section for a donor to provide information that goes only to the MRO. The donor is asked to put a telephone number where he/she can be reached. In this box, the donor can also list any medications he/she believes may affect the drug test. If you are taking a legally prescribed and dispensed medication that results in a positive test result, the MRO will report the test as a negative to the Department. However, there is virtually no valid medical explanation for a positive cocaine or marijuana test result. (See Rule 111, Appendix D).

7. What is a Safety-Net test?

The safety-net test is a test that an officer can request if he/she has a positive test result. It must be requested in writing within 72 hours of receiving notification of the positive test. This is not a complete re-test or another chance. Rather, it is a test to confirm that no mistake was made with the donor's hair sample. Another hair sample is taken, and the laboratory conducts a more stringent test, using lower cutoff levels. The officer pays for the test and the MRO review unless the test is negative, in which case the Department will pay for the test. Also, the Department will expunge the officer's IAD file of the

positive test result. (See Rule 111, Appendix D).

8. What are the consequences of testing positive for illegal drugs?

Drug testing is intended, in part, as a means of identifying those officers who need help. The Department's drug testing policy is intended to be humanitarian, combining both treatment and discipline for a first time offense. This Department is one of just a few police department in the country that offers an officer a second chance to keep his/her job after testing positive for illegal drugs, thereby minimizing the financial impact on the family and preserving a valued member of the Department.

Every officer that tests positive for the first time, if there are no other violations pending, is given the opportunity to accept the settlement/rehabilitation agreement, which includes a 45 working day suspension and participation in a treatment program. The officer is also subject to unannounced urine testing for three years to monitor the officer's recovery progress. If an officer refuses the settlement/rehabilitation agreement or tests positive a second time, termination is the only appropriate discipline. There is simply no room in the Department for an officer that continues to use illegal drugs.

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Exhibit 5



Date: 2/4/04

From: James M. Hussey
Police Commissioner

To: Deputy Supt. O'Malley

- | | |
|---|--|
| <input type="checkbox"/> E.Y.I. | <input type="checkbox"/> Your Comments |
| <input type="checkbox"/> Please Handle | <input type="checkbox"/> File |
| <input type="checkbox"/> Please See Me On This | <input type="checkbox"/> Please Advise |
| <input type="checkbox"/> Please Call Me On This | <input type="checkbox"/> Forward To |
| <input type="checkbox"/> Signature Please | <input type="checkbox"/> Other (See Below) |
| <input type="checkbox"/> Prepared for PC. | <input type="checkbox"/> As Requested |

Comments/Reply:

To be discussed at next weekly mtg.



1 Schroeder Plaza, Boston, MA 02120-2014

To: James M. Hussey
Acting Police Commissioner

Through: Superintendent Thomas A. Dowd
Chief, Bureau of Internal Investigations

From: Sergeant Detective Joseph T. Devlin, Jr.
Bureau of Internal Investigations

Date: December 11, 2003

Subject: AAMRO 2003 Annual Drug Testing Symposium

The American Association of Medical Review Officers (AAMRO) Annual Drug Testing Symposium, held from December 5 – 7, 2003, covered many areas, but several were of particular interest.

Most drug testing done for both private corporations and for government agencies consists of urinalysis testing and the majority of the laboratories in the U.S. are experts primarily in that type of testing. Nevertheless, there is an increased awareness of the efficacy of what are referred to as “Alternative Technologies”. The three alternative technologies covered in this year’s program are: **oral fluid testing, the drug abuse patch and hair testing.**

Oral Fluid Testing

Although it is becoming increasingly popular in Europe, chiefly as a means to check for blood alcohol level at the scene of an accident or traffic stop, oral fluid testing covers a much shorter time span than does any other type of testing. In a nutshell, urinalysis testing covers a window that begins within several hours after ingestion and extends out to 24 – 36 hours (perhaps slightly longer for marijuana use); the drug abuse patch measures use over a 24 hour to two week period and hair testing is designed to measure potential drug use over a 90 day period. While oral fluid testing can detect some drugs up to a maximum of 48 hours, a maximum of 24 hours is more likely. However, its chief benefit is that usage of cocaine, heroin and marijuana will appear in oral fluid within minutes of ingestion. Consequently, oral fluid testing can be highly useful as a means of conducting a non-invasive “post accident” test (or perhaps a “post incident” test for officers involved in a shooting incident). Arguably, it is also the best test to use if you want to know if a person is currently under the influence of drugs instead of using another testing process that only measures past usage, but does not measure a person’s current condition.

Drug Abuse Patch

A number of probation and corrections departments around the country and in Europe currently use the drug abuse patch to ensure that their probationers or parolees remain drug free. The drug abuse patch appears to be most useful in dealing with a population that normally has a high recidivist rate and is worn for a minimum of 24 hours up to a maximum of 14 days. Aside from measuring for drugs of abuse over a period of time, its chief benefit might be to allow a person who is afflicted with paruresis (shy bladder syndrome) to use an alternative testing procedure in situations where a urine test is currently mandated.

Hair Testing

John Irving, Laboratory Director for SureTest Laboratories (and the former Assistant Laboratory Director for Psychemedics) gave a presentation that detailed the testing process for drug hair tests done by Psychemedics. His presentation was very thorough and covered every facet of the drug hair test process, including the collection of the sample, the hair washing procedures and the type of both the initial and confirmatory tests done, i.e., RIAH, GC/MS, GC/MS/MS and LC/MS.

Dr. Yale H. Caplan, Director of National Scientific Services, gave a presentation on hair test technology generally, including allegations that such testing may be racially biased. Dr. Caplan related a number of the benefits of hair testing over urinalysis testing, such as the relative ease of obtaining, storing and shipping specimens and the increased number of "positives" in side by side testing with urinalysis. He also explained in detail how drugs that are ingested end up being stored in the hair. Dr. Caplan then explained some of the disadvantages, which amounted chiefly to the cost, the limited number of laboratories offering hair testing and the need for procedures to deal with individuals who may have little or no hair.

However, in my opinion, Dr. Caplan presented a very misleading and factually erroneous presentation to an entire room full of Medical Review Officers (MROs) when his portion of the lecture covered the topic of allegations of racial bias in hair testing. Dr. Caplan's presentation nurtured the belief that hair testing is potentially racially biased while presenting evidence that clearly shows no such thing and at most suggested a potential only for "hair color bias". Additionally, he totally glossed over any evidence that indicated that such a bias did not exist. Why?

Dr. Caplan is the former Director of Toxicology and Forensic Toxicology for Quest Diagnostics. He currently serves as an advisor to attorneys regarding alcohol and drug testing issues and has regularly testified as an expert witness in court. It is unclear if the firm he is now a director of, National Scientific Services, is a private drug testing lab or a consulting firm. One of the studies that Dr. Caplan referenced was authored by another presenter, Dr. Edward J. Cone. Dr. Cone currently serves as head of ConeChem Research, a private firm that provides consulting services on matters relating to drug testing and drug delivery systems. In fact, although their academic credentials and professional associations are impressive, most of the presenters at this conference currently work for (or own) private laboratories or consulting firms that have a vested interest in promoting one type of testing over another. While I doubt any of these professionals are being intentionally deceptive, I do believe that their individual biases tend to affect their judgement and their interpretation of study results.

One individual who was not at the conference is Dr. Thomas Mieczkowski. Dr. Mieczkowski is a professor in the Department of Criminology at the University of South Florida. Unlike those presenters who previously or currently work for laboratories and/or consulting firms, Dr. Mieczkowski is a professor and researcher who has analyzed past studies conducted on hair drug testing as well as having conducted studies of his own (see attached copies of studies and/or abstracts). His findings conclude that any evidence of racial or hair color bias is either statistically insignificant or is no greater than statistical variances that exist within racial or ethnic groups. Lending further credence to the results of his research, Dr. Mieczkowski has conducted several large scale studies (one of which included over 56,000 subjects) instead of the poorly designed, small scale studies that are frequently cited by others to discredit the reliability of hair testing.

Synthetic Opiates

It had never occurred to me that the most common prescription drugs of abuse might elude our current drug testing process, but there is a very strong likelihood that is the case. The two most common drugs of abuse are classed as synthetic opiates: Hydrocodone (a/k/a Vicodin) and Oxycodone (a/k/a Oxycontin, Percocet, Percodan, et al). There are two problems evidenced with these types of drugs.

One, a standard drug screen testing for the presence of opiates may not show the presence of a synthetic opiate. This is true for Oxycodone, but not for Hydrocodone (which will normally show up on a standard opiate screen). Two, even if the standard opiate drug screen tests positive for opiates, the confirmatory test will yield a negative result. There is a specific drug screen that can be used to test for the presence of Oxycodone. While there is no specific drug screen that can be used to test for the presence of Hydrocodone, it can be identified using a GC/MS test.

Anecdotally, abuse of pain relieving drugs like Hydrocodone and Oxycodone is relatively common, but our testing process is probably not indicating the presence of either drug in those we test. Considering how many of our officers are injured in the line of duty and are presumably prescribed pain relieving drugs during the early stages of their injury, the failure to ensure that our drug tests detect such drugs is a flaw in the testing process that needs to be corrected.

At a minimum, I recommend that the labs conducting both our hair tests and our urinalysis tests be instructed to include a specific drug screen for the presence of Oxycodone in all drug tests. Likewise, I recommend that a GC/MS test for the presence of Hydrocodone be conducted whenever an individual tests positive in the initial screen for opiates, but tests negative for opiates in the confirmatory test. While there are many other synthetic opiates on the market, initiating these two recommendations will at least test for the two most common drugs of abuse.

Exhibit 6

Thomas Michael Mieczkowski

Curriculum Vitae

October 31, 2003

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ACADEMIC AND PROFESSIONAL PREPARATION

DATES	INSTITUTION	GRADUATION	DEGREE
1980 - 1985	Wayne State University, Detroit, MI Sociology/Criminology with Anthropology (cognate)	December, 1985	Ph.D.
	Dissertation Street Selling Heroin: The Young Boys Technique in a Detroit Neighborhood		
1974 - 1976	Wayne State University, Detroit, MI Sociology/Criminology	June, 1976	M.A.
	Thesis: Syndicated Crime in the Caribbean		
1965 - 1969	Wayne State University, Detroit, MI	June 1969	B.A. (Sociology/Biology)

CURRENT POSITION

1989 – present	PROFESSOR College of Arts and Science / Criminology	The University of South Florida, Tampa, FL
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PROFESSIONAL EXPERIENCE: TEACHING

1979 - 1985	TEACHING ASSISTANT , Sociology Department	Wayne State University Detroit, MI
1986 -1989	LECTURER, ACTING CHAIR (1988/89) Department of Criminal Justice	Wayne State University Detroit, MI

Thomas M. Mieczkowski

1989 - 1992	ASSISTANT PROFESSOR Department of Criminology	The University of South Florida, St. Petersburg, FL
1992 - 1996	ASSOCIATE PROFESSOR Department of Criminology	The University of South Florida, St. Petersburg, FL

PROFESSIONAL EXPERIENCE: RESEARCH (GRANTS AND CONTRACTS)

1983 - 1985	Thomas Rumble Fellowship, Doctoral Dissertation Grant	\$10,000.00
1986-87	Zalman, M. (P.I.), Mieczkowski, T. (Co-I), "Mathematical Forecasts of the Michigan Prison Population Through the Year 2000," Michigan Department of Corrections Research Grant	\$80,000
1987	Mieczkowski, T. (P.I.) Pilot Study, , National Drug Use Forecast Study, National Institute of Justice	\$7,000
1987-89	Mieczkowski, T., Project Manager, Drug Use Forecast System, Detroit, Michigan, National Institute of Justice	\$114,000
1988-89	Mieczkowski, T., Projector Director, Drug Use Forecast Training Project, Open-ended Services Contract. National Institute of Justice	\$10-20,000 (est. value)
1988 - 1989	Mieczkowski, T (P.I.), Boyd, C (Co-I) "Crack Use in Detroit," Bureau of Justice Assistance	\$10,000
1988-1989	Mieczkowski, T. (Co-P.I.), Landress, H. (Co-PI), Economic Addiction Study, Pinellas County Juvenile Welfare Board	\$5,000
1990-1991	Mieczkowski, T., (P.I.), Utilization of Radioimmunassay of Hair for Drug Use Prevalence Estimations in Arrestees, National Institute of Justice	\$30,000
1990-1991	Mieczkowski, T. (P.I.), Analysis of Self-Report and Concordance Data from 300 Arrestees in Pinellas County, National Institute of Justice	\$100,000
1991	Mieczkowski, T. Travel Grant, Presentation to the Harvard Epidemiology Working Group, Harvard University, School of Public Health	\$1,000
1991	Mieczkowski, T. Travel Grant, Presentation to the International Association of Forensic Toxicology, Genoa, Italy, The Psychemedics Corporation	\$2,000

Thomas M. Mieczkowski

1992-1993	Mieczkowski, T. (P. I.) "Hair Assays for Drugs of Abuse in a Probation Population: Implementation of a Pilot Study in a Correctional Field Setting", National Institute of Justice	\$210,000
1993-1994	Mieczkowski, T. (P. I.) "Hair Assays and Urinalysis for Drug Use Among Juvenile Offenders: A Comparison of Two Cities Based Upon the Drug Use Forecasting Program", National Institute of Justice	\$200,000
1993	Mieczkowski, T. Travel Grant, Presentation to the International Association of Forensic Toxicology, Genoa, Italy, The Psychemedics Corporation	\$2,000
1994-1995	Mieczkowski, T. (P. I.) "Epidemiology of Substance Abuse in Pregnancy: An Examination of Prevalence with Postpartum Mothers", Center for Substance Abuse Prevention	\$50,000
1995	Mieczkowski, T. Travel Grant, Presentation to the International Association of Forensic Toxicology, Genoa, Italy, The Psychemedics Corporation	\$2,000
1996-1997	Mieczkowski, T. (P.I.) "Drug Monitoring in Criminal Justice Management Applications: Integrating the Ion Mobility Spectrometer into the New Orleans Pretrial Diversion Program," National Institute of Justice	\$150,000
1997-1998	Mieczkowski, T. (P.I.) "State Demand and Needs Assessment Studies: Alcohol and Other Drugs, Florida: Criminal Justice Component. Center for Substance Abuse Treatment	\$90,000
1997	Mieczkowski, T., Travel Grant The International Symposium on Youth Education, The National Institute for Health Sciences, Tokyo, Japan	\$12,000
1998	Mieczkowski, T. (P.I.) "Pilot Study: Needs Assessment of the ADAM Instrument: Pinellas County, Florida", National Institute of Justice	\$8,200
1998-2000	Mieczkowski, T. (P.I.) "The Use and Evaluation of Hair Analysis and Ion Mobility Spectrometry in a Juvenile Diversion Program in New Orleans", The National Institute of Justice	\$200,000
1999	Mieczkowski, T. Travel Grant, Presentation to the International Association of Forensic Toxicology, Martigny, Switzerland, The Psychemedics Corporation	\$10,000
2000-2001	Mieczkowski, T., Sabbatical Research Fellowship, The Psychemedics Corporation	\$38,000

PROFESSIONAL AND ACADEMIC MEMBERSHIPS

American Society of Criminology

The International Association of Forensic Toxicology

British Academy of Forensic Sciences

The European Hair Research Society

Affiliate Faculty, Center for Substance Abuse Research, University of Michigan

PUBLICATIONS, BOOKS

Mieczkowski, Tom (Ed.) Drug Testing Technologies:Field Applications and Assessments. Boca Raton, Florida, CRC Press, 1999.

Mieczkowski, Tom (Ed.) Drugs, Crime, & Social Policy. Boston, MA: Allyn and Bacon, 1992.

PUBLICATIONS, CHAPTERS IN BOOKS AND MONOGRAPHS

Mieczkowski, T. (with Kim Lersch). "Armed and Dangerous: Exploring Police Drug Use and Drug Related Corruption", forthcoming, A. Piquero, J. Green (eds.), Wadsworth Press

Mieczkowski, T. (2002). Drug Testing Methods and Analysis, in R. Carter-DeWitt (Ed.) Drugs, Alcohol, and Tobacco, MacMillan, New York.

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Mieczkowski, T. "Drug Screening Technologies: A Review of Capacities, Limits, and Issues Influencing Interpretation of Drug Tests in Clinical and Field Settings", 2001, Addiction Recovery Tools: A Practitioner's Handbook (R. Coombs, Ed.), Sage Publications, Newbury Park, CA.

Mieczkowski, T. "Drug Abuse, Corruption, and Officer Drug Testing: An Overview ", 2001, in Policing and Misconduct (K. Lersch, Ed.), Prentice Hall, Saddle River, NJ.

Mieczkowski, T. "The Utilization of Ion Mobility Spectrometry in a Criminal Justice Field Application", 2000, in Drug Testing Technologies:Field Applications and Assessments, pp. 73-90 (T. Mieczkowski, Ed.), CRC Press, Boca Raton, Florida.

Mieczkowski, T. & Newel, R."Drug Monitoring in the Field: Applying Hair Assays and Urinalysis for Cocaine to Probationers", 2000, in Drug Testing Technologies:Field Applications and Assessments, pp. 125-144 (T. Mieczkowski, Ed.), CRC Press, Boca Raton, Florida.

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Mieczkowski, T. (2000). Any Visible Admixture: Revisiting Race as an Analytic Variable in Research, Social Pathology 6(3):165-182.

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Mieczkowski, T., Tsatsakis, A., Psillakis, A., Kruger, M. (2001). The Concentration of Three Anti-seizure Medications in Hair: The Effects of Hair Color, Controlling for Dose and Age., BMC Clinical Pharmacology 1(2): 1-33.

Mieczkowski, T. (2001). The Effect of Color and Curvature on the Concentration of Morphine in Hair Analysis. Forensic Science Communications 3(4):1-5.

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Mieczkowski, T., Lersch, K., Kruger, M. (2002). Police Drug Testing, Hair Analysis, and the Issue of Race Bias, Vol. 27, #1, Criminal Justice Review

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Bazley, T., Mieczkowski, T. (2003). Researching Workplace Violence: The Utility of the Supplementary Homicide Reports. In Press, Journal of Criminal Justice

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Mieczkowski, T. (1994). Epidemiological Data and Hair Analysis: Current Findings on Self-Reported Drug Use, Urinalysis, and Hair Assays. Proceedings of the Consensus Conference on the Use Of Hair Assays for Measuring Drugs of Abuse, The International Association of Forensic Toxicology/The Society of Forensic Toxicology.

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ABSTRACTS

Thomas M. Mieczkowski

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Thomas M. Mieczkowski

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"Investigating Potential Differences between Cocaine Users and Distributors Using the Ion Mobility Spectrometer", invited lecture, College of Science and Technology, Central Michigan University, March 16, 2000.

"The Racial Bias Controversy in Hair Assay Interpretation", presentation to the staff of the Department of Pediatric Toxicology, The Hospital for Sick Children, University of Toronto, November 24, 1999.

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"A Statistical Examination of Hair Color as a Potential Biassing Factor in Hair Analysis", paper presented at the Annual Meetings, The European Hair Research Society, Martigny, Switzerland, June, 1999.

"The Use of Hair Analysis and Other Bioassays in Drug Control Policy: An Overview", Congressional Testimony, United States House of Representatives, Committee on Government Oversight and Reform, Subcommittee on National Security, June 5, 1998

"The Use of the Ion Mobility Spectrometer in The New Orleans Diversion Program: A Two Year Review of Performance", presentation to the Office of National Drug Control Policy, New Orleans, Louisiana, May 14, 1998.

"Applications of New Technology to Drug Detection", lecture presented by invitation at the Royal Medical Society, London, England, January 9, 1998.

"The Use of IMS and Comparative Outcomes for Hair and Urine Testing Protocols", paper presented at the American Society of Criminology Annual Meetings, San Diego, CA, November 26, 1997.

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"Harm Reduction," round table discussant, by special invitation, The University of Michigan Substance Abuse Research Center, The University of Michigan, Ann Arbor, May 6th and 7th, 1997.

Thomas M. Mieczkowski

"Interpretation of Hair Analysis of Drugs of Abuse: Passive Contamination and Bias Issues," paper presented at the Annual Meetings, the American College of Occupational and Environmental Medicine, Orlando, FL, May 16, 1997

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1981 President, Graduate Student Organization
1982 Recipient, Thomas Rumble Professional Fellowship
1983 Qualifying Examination Passed with Special Distinction
1983 Nominee, President's Young Scholar Award
1984 Lecturer, Graduate Honors Symposium Wayne State University
1988 Certificate of Technical Merit National Institute of Justice
1988 Member, City of Detroit Task Force on Drug Issues, City Department of Health and Human Services

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Exhibit 7

Distinguishing Passive Contamination from Active Cocaine Consumption: Assessing
the Occupational Exposure of Narcotics Officers to Cocaine

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Introduction

Cocaine is a drug which appears to be used at very high rates in populations undergoing treatment for drug abuse as well as criminal offender populations. However, it is relatively difficult to detect cocaine by urinalysis except in the immediate day or two after it is consumed. As a consequence the true prevalence rate for cocaine use remains unknown, and estimates for this rate which rely solely on reporting of use have consistently proven to be underestimates (Brookoff, Campbell, Shaw 1993). Furthermore, cocaine's rapid excretion rate also makes defeating urine testing relatively easy. For example, in many criminological settings (such as probation or parole management) the combination of high caseload, the client's ability to delay an appearance for a testing appointment, or deliberate evasive maneuvers such as the use of diuretics, have all contributed to a relatively low credibility of the true detection efficacy of urine testing in routine monitoring circumstances (Mieczkowski, Newel, Allison, Coletti 1994). A nascent industry has emerged, devoted to helping persons "beat" their urinalysis tests, and operates openly and legally in most major urban areas around the United States.

Hair analysis has been proposed as a desirable alternative or supplement to urine testing. It has already been employed as a monitoring technology in several criminal justice contexts, including intensive probationary supervision programs, work release programs, experimental programs designed to monitor routine probationers, and pretrial diversion programs. A literature has also accumulated on the effectiveness of hair analysis in these roles, and generally these reviews have been positive, especially in regards to the increased ability to detect cocaine exposure (Mieczkowski, Newel 1993; Baer, Baumgartner, Hill, Blahd 1991; Mieczkowski, Mumm, Connick 1995; Knight, Rowan-Szal, Hiller, Chatham, Simpson 1995; Magura, Freeman, Siddiqi, Lipton 1991; Magura, Kang, Shapiro 1993; Magura, Kang 1994). Hair analysis has also withstood court examination of its suitability as evidence. To date hair assays results have been accepted in most criminal and civil cases in which they have been introduced as evidence, up to the level of the Federal District Court (see for example, Nevada Employment Security Department v Cynthia Holmes, Supreme Court, State of Nevada #26157 or United States v. Anthony Medina. 1990. 749 F. Supp. 59; U.S. District Court, New York).

The Fundamentals of Hair Assay Technology

Hair analysis is based upon the premise that many drugs become entrapped and stabilized in the keratin matrix of hair. This trapping appears to be especially effective for cocaine (Wang, Cone 1995) and is well demonstrated even at low dosages, as shown by the work of Henderson et al. (Henderson, Harkey, Jones 1993). Entrapped drugs appear to enter hair by several routes; from the plasma, transcellular diffusion during keratinization, sweat and sebum bathing, etc. These materials, acquired in the development of the hair, appear to be firmly held in microstructural elements of the hair. Once bonded to these elements the materials are not able to be removed by extensive

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washing. In hair analysis these analytes are accessed by hair digestion or extraction procedures whose aim is to liberate and identify the particular chemical entities under scrutiny. It appears that with cocaine and several of its various metabolic products this sequestering is extremely stable (Cartmell, Aufderheide, Springfield, Weems, Arriaza 1991). As well, the amount of cocaine use in terms of gross quantities of substances ingested, appears to bear a discernible relationship to the concentration attained in hair, provided it is measured over a sufficiently wide dosage range. Cocaine and other entities are also capable of attachment to hair via environmental exposure, but they do not appear to attain the same bonding or attachment strength, under normal circumstances, as do drugs which are ingested. These environmentally acquired drugs, in most circumstances, can be removed by appropriate washes.

The primary advantage of hair analysis is the relatively long retrospective identification of classes of drugs which normally quickly disappear from blood or plasma. Cocaine and several other popularly abused psychoactives are stable when embedded in the hair and can be detected for months, and in some cases even years, after exposure. A second advantage is quantifying the drug recovered in the hair and estimating from that value the amount of drug ingested [i.e., establishing a dose/assay relationship]. The dose/assay relationship appears to be limited in its utility to a rank-order assignment of values. There are relatively high degrees of inter-subject variability regarding the regression relationship between dose consumed/drug recovered. However, hair appears useful for tracking drug exposure within individuals, where a baseline value is established for any given individual and they can subsequently act as their own control (Martz, Donnelly, Fetteroff, Lasswell, Hime, Hearn 1991; Brewer 1993; Williams 1995). Some research has shown that good correlation exists between self admitted cocaine use and hair assays values (Hoffman, Wish, Koman, Schneider, Flynn, Luckey 1993), that the probability of having a cocaine positive urinalysis outcomes and the quantitative value of a cocaine positive hair specimen are very strongly positively related (Mieczkowski, Newel 1993), that cocaine concentration values attained in the hair are positively related to the efficiency of the consumption method (Mieczkowski, Newel 1994), and that the correlation between maternal and neonatal hair assays for cocaine is quite strong (Marques, Tippetts, Branch, 1993; Graham, Koren, Klein, Schneiderman, Greenwald 1989; Callahan, Grant, Phipps, Clark, Novack, Streissguth, Raisys 1992; Welch, Martier, Ager, Ostrea, Sokol 1990).

The use of hair as a specimen for toxicological identifications is not novel. Hair was first used in criminal proceedings in the United States in the nineteenth century, with testimony about hair analysis first admitted in 1882 in *Knoll v. State*, 55 Wis. 249, 12 N.W. 369 (Imwinkelreid, 1991). The first reported recovery of a psychoactive drug from the hair of guinea pigs was published in the United States more than 40 years ago (Goldblum, Goldbaum, Piper 1954). In recent years concern with drug monitoring has created sufficient demand to make development of a low-cost, immunoassay based screening technology economically attractive. This has resulted in several commercial laboratories in both the U.S. and Europe developing and offering hair analysis services to detect psychoactive drugs. In a recent laboratory evaluation exercise, for example, eleven different laboratories participated in a round-robin review to detect cocaine and

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morphine in hair samples (Welch, Sniegoski, Allgood, 1993).

Hair Analysis of Cocaine Exposure and Its Controversies

The identification of cocaine and its metabolites in hair has, itself, not been particularly controversial. Virtually all published research has shown that cocaine, as well as its major metabolites, can be readily identified in hair by a wide variety of analytic techniques, including the use of radioimmunoassay [RIA], high performance liquid chromatography [HPLC], gas chromatography/mass spectrometry [GC/MS], and gas chromatography/tandem mass spectrometry [GC/MS/MS] (Moeller 1992). As with all diagnostic procedures controversy has arisen, however, about how to interpret the detection of drugs in hair (Kintz, Mangin 1995). Clearly, the detection of a substance in hair is an indication of **exposure** to that substance. Indeed, as Kidwell (1996) has noted:

"Certainly, many positive hair analysis results are due to ingestion of drugs but passive exposure must be considered when evaluating any particular case. What does hair analysis for drugs of abuse measure? It measures exposure. Methods to distinguish use from exposure are still undiscovered."

The crux of the controversy is contained in the last statement, namely the determination of the nature or cause of exposure. If the individual denies using the drug, what is its source? This interpretative problem has intensely focused on the issue of **passive contamination** and the ability to distinguish passive exposure from active (i.e. willful, knowing) ingestion (Kidwell, Blank 1995).

The term "passive contamination" is generally used to describe cocaine which has been environmentally deposited on the surface of the hair. A second, related issue is **passive ingestion**. Passive ingestion generally is taken to mean the secondary consumption of cocaine via inhalation of smoke, oral contact, or other similar acts by which small traces of cocaine are actually consumed, but not consumed willfully or knowingly by the person. This can result from known contact with persons who use cocaine (e.g., kissing a person who has just smoked crack cocaine), or could result from unknown contact with contaminated persons or objects. Passive and active ingestion are not biochemically distinct, of course. But, as a practical matter, under most clinical circumstances passive ingestion entails microscopic (nanogram) quantities of a drug, while active ingestion usually involves taking thousands of milligrams of the material.

Some confusion exists regarding the concept of contamination and the deposition of cocaine into hair from sweat or sebum. The sweat of a cocaine user contains cocaine, and this source of cocaine is often reflexively treated as "environmental contamination." Cocaine deposited into hair via the sweat of the individual cannot be considered as an environmental contaminant, since the cocaine arises from an endogenous source, namely the various somatic pools of drug in plasma, cellular fluids, etc. Thus while sweat may make some contribution to the total

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quantity of drug found in the hair of the drug user, its role does not represent a problematic one from the point of view of identification of drug users. Contamination via sweat between persons, which would be true environmental contamination, may occur with chronic and prolonged skin-to-skin contact, or the sharing of wet clothing, applied to hair, and heavily laden with sweat. However, no study has shown that such contamination would be confused with cocaine arising from endogenous sources, although specific studies examining this issue should continue to be pursued. The circumstances under which this type of inter-person sweat transfer might occur would be rather specialized, and do not appear to be frequently encountered in clinical populations studied. Problems of this sort are normally resolvable by extensive washing of samples with water or methanol.

Clinical Determinations of the Source of Drugs Found in Hair

One erroneous characterization of clinical application of drug analysis is that practitioners do not utilize assays in a diagnostic fashion, i.e., as merely one a series of informational items upon which a decision is based, but rather in a sort of "all or none" fashion. For example Kidwell (1996) states that:

"Those using hair analysis seek a definitive yes/no answer to the question: Did this individual ingest drugs? An individual's mere contact with drugs is seldom at issue."

This statement is not accurate. While it may be true in some circumstances that critical decisions are made on the basis of a single assay outcome, this is not true for most other uses of drug analysis. In criminal justice and treatment monitoring, as well as employee assistance programs, actions taken in response to apparent drug use arise out of long-term relationships and assessment periods, and consideration of multiple measures of drug involvement.

Furthermore, the term "mere contact," as Kidwell labels the phenomenon, obscures the clinical significance of the difference between trivial, microscopic levels of contamination and massive, overwhelming levels of contamination. The determination of massive exposure to an illicit drug is indeed relevant to criminal justice monitoring, treatment program monitoring, and a variety of security-based drug monitoring contexts. For example, what is called "mere contact" may be a critical issue in a court-supervised diversion program where a condition of participation is to avoid contact with drugs, places where drugs are bought and sold, and social associations with drug users. A person showing high degrees of cocaine contamination on their clothing, etc. would be a situation of clinical and legal concern. Likewise the massive contamination of an infant by cocaine would be of importance. Kidwell's statement implies that those who utilize hair analysis are (or perhaps ought to be) unconcerned about cocaine exposure, but are (or can legitimately be) concerned with cocaine use. It would be more accurate to state that those using hair analysis for cocaine detection seek an answer to the question "did the individual experience trivial, incidental, or meaningless exposure that can be plausibly explained by background effects, or is this exposure of a

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magnitude that calls into question the person's denial of cocaine use or involvement?"

In clinical use, the outcome of a single hair assay is rarely treated as a definitive informational item. Rather, it is treated as one of a series of informational items, all gleaned from various sources available to the clinician. The gathering of information regarding a final decision on the interpretation of an assay depends on both available concomitant data (e.g., urine testing, saliva testing, interviewing, etc.) as well as historic data (e.g., how does this assay value rank relative to other assays taken in the past?) A little-mentioned but important aspect of clinic experiences with both hair and urine testing in criminal justice and clinical treatment contexts is that challenges are very rare and self-admissions are the norm (Brewer 1993; Knight , Rowan-Szal, Hiller, Chatham, Simpson, 1995). A simplified flow diagram illustrating this process is shown in Figure 1:

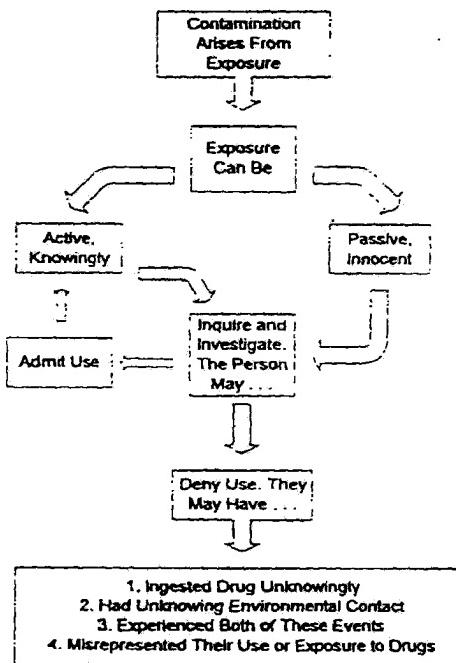


Figure 1. A Decision Tree for Assessing Contamination

Passive Contamination and Wash Processes

Hair, being on the exterior of the body, is subject to environmental contact and hence contamination. Drugs can be readily deposited on hair from environmental sources, such as dust, smoke, or aqueous sprays. Critics of hair assays contend that hair analysis cannot adequately distinguish between active use and inadvertent environmental contamination because environmentally deposited cocaine tightly bonds to hair, and cannot be removed (Kidwell, Blank 1995). This effectively obliterates the difference between surface-contamination and cocaine which may enter the hair from the consumption of cocaine. Alternately, others have argued that wash procedures,

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properly done, can remove all or nearly all of any normally acquired environmental contaminants (Baumgartner, Hill 1990; Koren, Klein, Forman, Graham 1992).

The argument that any environmental contamination, no matter how small, renders hair assays unreliable is not accurate. Hair assay interpretation does not need to assume that the hair is absolutely free of any trace of contamination. The simple value of the drug extracted from hair is not used by itself to determine the outcome of the assay. The procedure compares the outcome from specific sequential washes applied to the hair with drug recovered from the hair. Interpretation of a hair assay, relative to passive environmental contamination, relies on several pieces of information; how much drug, if any, is discovered in the various wash series (which are done to cleanse the hair and identify any contaminants), and second, how much residual drug remains in the hair after the wash procedure is completed. Thus hair assay values/wash assay values must attain a **series of specific ratios** to be properly interpreted. Baumgartner and Hill (1992) have developed the most specific of these criteria. They are presented below in Table 1.

Table 1. Wash Kinetic Criteria of Baumgartner and Hill

Criteria	Calculation	Required Ratio
Extended Wash Ratio	amt. of drug per 10 mg hair in digest amt. of drug per 10 mg hair in last PO ₄ wash	> 10
Safety Zone Ratio	amt. of drug per 10 mg hair in digest amt. of drug per 10 mg hair in all 4 PO ₄ wash	> 0.33
Curvature Ratio	amt. of drug per 10 mg hair in 3 PO ₄ wash 3 times the amt. of drug per 10 mg hair in last PO ₄ wash	> 1.3

Positive specimens must pass all three criteria to be considered a cocaine positive. Additionally, one can also utilize assays to detect the presence of cocaine metabolites, typically benzoylecgonine [BE], ecgonine methyl ester [EME], norcocaine [NE] and cocaethylene [CE]. The presence or absence of these metabolic products adds further information in interpreting a particular assay outcome. The use of metabolites is premised on the observation that these arise largely or exclusively from internal metabolic processes which occur in the body, or they are not typically found in cocaine hydrochloride or "crack" cocaine as it is vended. Rather than rely on the simple presence or absence of these substances, one can use ratios of the parent drug to the metabolite in order to help in interpreting the assay outcome. For example, Cone (1994) has suggested that the presence of CE and NE are indicative of active drug use and that BE/cocaine ratios which exceed a value of 0.05 are also indicative of active drug use. Koren and his colleagues have argued for a similar interpretive approach (Koren, Klein, Forman, Graham 1992), as have Baumgartner and Hill (1992).

The problem of passive, inadvertent ingestion is one which presents a somewhat different interpretive issue. Because passive ingestion can produce the same qualitative biological outcome and same metabolic outcomes as "knowing use" one must take the same approach as has been done with urinalysis. This requires an operational assumption that casual, inadvertent "use" (i.e., ingestion) normally differs

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substantially in quantitative dimensions from active use. This is essentially a statistical distinction. Inadvertent users and deliberate users have the same experience, in a qualitative biological sense. However, they do not have the same experience in a quantitative sense. Inadvertent use (except under the most bizarre circumstances) is an event premised on minor exposure, while wilful use is an event which typically is characterized by large-scale consumption, especially for cocaine abusers.

The Use of Threshold Criteria

When it is necessary to control for passive ingestion of cocaine (e.g. by passive inhalation of crack smoke, by contamination due to exchange of body fluids such as semen or sweat), hair analysis uses the same methodology as urinalysis, statistically-based cut-off values. The value of the assay must exceed a specific threshold in order to be labeled as a diagnostic positive outcome. This is quite distinct from a technical positive. A technical positive is defined by the analytic technology's limit of detection [LOD]. A diagnostic negative test may result from a specimen that is technically positive. That is, the specimen has a technically detectable amount of the particular analyte present, but an insufficient amount of the drug is recovered to "cross" the cutoff threshold.

Where should such a threshold be established? Unless one decides that the LOD is appropriate, there is no technically imposed answer to this question. The threshold represents a marker at which it is generally recognized that explanations of passive or inadvertent exposure are implausible. This is intrinsically a statistical phenomenon and is related to the scatter caused by biochemical clinical individuality and the correlation between dosage and cocaine levels in hair. Unlike urine, the statistics of hair analysis are not effected by excretion kinetics. Kintz and Mangin (1995) have addressed this issue and recommend a "stand alone" value for cocaine of 1 ng/mg of hair (i.e., by "stand alone" is meant that hair is used in the absence of any other corroborating specimen), and suggest that this cut-off may be lowered to 0.5 ng/mg when "supported by other evidence of drug intake." Baumgartner and Hill (1995) have argued for the use of a 0.5 ng/mg cut-off value.

In clinical practice there is no need to require a universal cutoff value for all monitoring circumstances. Indeed, in current practice there are a wide variety of thresholds employed in urinalysis testing for cocaine, dependent on the perceived needs of the testing program and its goals. For example, over the last two decades the thresholds for cannabinoids has been consistently edged downwards in response to epidemiological reports that initial values were so high as to produce substantial numbers of diagnostic false negative urinalyses. Quite unlike other illicit drugs, marijuana has been shown to often be over-reported; that is, more people report marijuana use than are identified by either hair or urine assays (Mieczkowski 1990). The lowering of cannabinoid cutoff values was not based on any theoretical model, but solely on clinical experience.

The selection of thresholds varies considerably in clinical practice. Commercial

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test kits are readily available to test urine for cocaine at a threshold of 25 ng/mg, even though in the U.S. the federal government employs a threshold in its workplace testing more than ten times this value. Some clinical programs have utilized a "zone" approach to interpretation of assays values (Mieczkowski, Mumm, Connick 1995). In this setting - a criminal justice based treatment program - persons testing positive for cocaine in hair at values between 0.5 and 3.5 ng/mg are monitored with increased scrutiny but are not presumed to be using the drug. Those who test positive at values greater 3.5 ng/mg are treated as users, unless some compelling alternative explanation is apparent. Over the history of this program these particular cutoffs, based on actual clinical conditions and experiences of the treatment staff, and have proven to be very useful. The clients are also randomly urine tested, consistently interviewed and counseled, and subject to surface contamination analysis. Program clients also have long-term clinical histories and a baseline hair assay value determined at program intake. Thus hair assay value changes for an individual are tracked over time. All this data is weighed and evaluated as potentially corroborating or clarifying information available to lend support to a particular case analysis. The effectiveness and utility of hair analysis in this context serves as an example of the prudent and careful use of hair assay technology. It contradicts the assertions that hair assays are inevitably used as simple binary indicators of cocaine ingestion.

Laboratory-Based Contamination Studies

Laboratory studies have shown that hair can be contaminated by cocaine. These studies have been criticized, however, because they have generally used "extreme contamination scenarios" in order to simulate contamination (Baumgartner, 1993). Laboratory studies have typically depended on prolonged aqueous soaks of hair in concentrated cocaine solutions, or suspensions of hair samples over pyrolyzed cocaine base (Wang, Cone 1995). There are problems in linking these *in vitro* studies to the hypothesis that casual contact, such as inadvertent touching of cocaine contaminated objects, could contaminate the hair of a non-user by subsequent touch. While clearly a contamination event is likely to occur, the issue is whether this contamination is so severe as to obliterate the distinction between use and non-use. It has been suggested, for example, that simple and transitory touching of contaminated objects could result in a positive hair assay and might lead to the labeling of an innocent person as a cocaine user (Henderson, Harkey, Jones 1993). On a practical level, for example, could a barber who cut the hair of a crack smoker then transfer sufficient cocaine to other customers by physical contact to the degree that wash procedures and cutoff values could not distinguish such persons from the crack smoker?

Such an event has never been demonstrated in any field setting and studies which have reported on field-based sample do not support the argument that such a phenomenon represents an impediment to the use of hair analysis. Contamination by physical touch appears to require rather specific or peculiar conditions to be significant enough to confound a properly executed assay. Avolio, Kim, and Radwanski (1994) have shown, for example, that dry hair samples placed in physical contact with cocaine-impregnated silica, removed periodically, and washed with methanol, did not begin to

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acquire methanol-resistant cocaine contamination even at the picogram level until after approximately seven days of continuous contact.

In general, the literature reveals that studies have distinguished quite readily between known cocaine users and known cocaine abstainers when those studies have been done under controlled conditions (e.g., see Cone, Yousenejad, Darwin, Maguire 1991). Koren et al. (1992) reported on both laboratory based hair sample manipulation as well as the exposure of human volunteers to cocaine contamination. In one study they had human volunteers exposed to 100 mg of vaporized cocaine in a confined space, and reported an average concentration for cocaine of 27 ng/mg of hair, and no detection of BE. Subsequent washing of the volunteers' hair resulted in removal of both cocaine and BE below the LOD. Wang and Cone (1995) exposed hair samples *in vitro* and also exposed human volunteers to similar amounts of vaporized cocaine under conditions similar to Koren et al. They reported comparable values for initial contamination concentrations. They reported that hair samples - vapor contaminated by 100 mg of vaporized cocaine, and soaked for 24 hours in a small volume of mild commercial shampoo - showed substantial loss of the contamination. The contaminated hair had initial values of 19.6 ng/mg in the wash fragment and 7.3 ng/mg in the extract. After one shampoo wash cycle, no cocaine could be detected in the wash fragment, and 0.7 ng/mg were detected in the hair extract. After the third shampoo wash cycle the cocaine values in the extract reduced to 0.4 ng/mg. A very similar pattern was reported for the cocaine pyrolysis metabolite anhydroecgonine methyl ester (AHE).

The two cocaine vapor-exposed human volunteers examined by Wang and Cone attained a mean value for cocaine of 29.5 ng/mg in the wash fraction and 7.1 ng/mg in the extract. They had concentrations of 6.2 ng/mg and 1.8 ng/mg for AME. After eight days of routine hair hygiene the wash values for cocaine had reached zero for one volunteer and 0.5 ng/mg for the second. The extract values were 0.6 and 0.5. The AME values were zero in both wash and extract fractions for both volunteers after eight days. Wang and Cone found that aqueous contamination, as opposed to vapor, resulted in elevated values for initial contamination readings in hair samples. However under mild and moderate soaking conditions repeated shampooing (up to 10 cycles) removed substantial amounts of the cocaine contaminants. In the mildest soaking scenario (0.01mg/ml HCL solution), cocaine recoverable from washing was zero and the concentration reduction in the extract fraction was 94.3% after the second wash cycle. By the tenth wash cycle the cocaine reduction was slightly greater than 99.5%. As the soaking solutions concentration were increased, the washing was less effective in removing the cocaine. Some hair samples were subject to a five-fold and a hundred-fold increase in soaking concentrations (.05 and 0.1 mg/ml). In each case, after 10 shampoo washing cycles, the percentage of original contaminant removed exceeded 99% of the original contaminant concentration. Also notable in Wang and Cone's report is that in the cocaine hydrochloride aqueous soaks BE was either absent or quickly removed by a single shampoo cycle. And in a contamination scenario in which the hair was contaminated with cocaine and added BE, the BE values dropped rapidly after shampooing, and approached or attained zero values.

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Field-Based Contamination Studies: Background Contamination by Cocaine

Another source of information on the plausibility of the contamination problem for hair assays is to take field measurements in circumstances where cocaine contamination is likely to occur. Cocaine is known to be present as an environmental contaminant. For example, it is widely recognized that a sizable percentage of United States currency is cocaine-contaminated. Also, it is quite plausible that any number of public objects are touched by cocaine users, potentially contaminated by them, and then these objects may, in turn, contaminate innocent persons touching these objects at a later time. Public drinking fountains, pay telephones, door handles and a host of other objects might be sources of cocaine transfer from users to non-users.

Field studies attempting to assess the degree to which this type of contamination occurs have shown that measurable amounts of cocaine are not easily transferred to hands by simply touching contaminated objects. Maloney, Barbato, Ihm, Nipper, and Cox (1994), for example, have shown that after handling cocaine-contaminated objects such as crack pipes, non-users failed to transfer measurable amounts of cocaine to their hands. Maloney and his colleagues also assayed the hands of bank tellers in a pre/post design to measure contamination of the hands based on handling cocaine-contaminated currency. Fifteen tellers from three different banks handled contaminated currency for the entirety of a normal four hour shift (and refrained from washing their hands at any time during the work period). Tests on the currency showed it to be contaminated with cocaine, but no cocaine was detectable on the hands of the tellers. They likewise were able to demonstrate that cocaine did not transfer to individuals who drove cocaine-contaminated vehicles which were seized from drug dealers by the police, even though the steering wheels of the cars tested cocaine positive. Nor could the researchers detect cocaine on public objects likely to be used by cocaine users or sellers such as pay telephones in high drug trafficking areas. The only scenario under which cocaine was readily transferred from contaminated person to negative control was under condition of direct skin-to-skin contact when volunteers handled "rocks" of crack cocaine, and then rubbed hands with negative control volunteers.

Ulvick et al. (Ulvick, Cui, Kunz, Demirgian, Hwang, Tani, Roche, Su, Rigdon 1996) and Demirgian et al. (Demirgian, Hwang, Ewing, Roche, Ulwick, Kunz, Su, Rigdon 1996) have also evaluated cocaine contamination, including the transference of cocaine from currency to persons. They concluded that while the total percentage of American currency in circulation contaminated with cocaine is "very high", currency with high levels of cocaine near the surface are "much rarer." By examining contaminated currency with scanning electron microscopy, they determined that currency can be contaminated by direct contact with cocaine, but "soon after initial contact most of the cocaine falls off." Some remnant cocaine penetrates the subsurface, but this cocaine, which is trapped in the currency's fiber matrix, does not contaminate the hands unless the surface is abraded by "hard rubbing". These findings explain why Maloney et al. were unable to detect any contamination on the hands of bank tellers, even after many hours of handling currency which was cocaine contaminated. Demirgian et al. (1996) also found that "contamination did not occur by normal handling of highly contaminated

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bills" and Ulvick et al. (1996) also concluded that their data "indicate that transmission of cocaine from currency to a person is unlikely." As well, Demirgian et al. also examined the potential for cocaine contamination by placing highly contaminated experimental subjects into a motor vehicle with negative control subjects. These person spent several hours driving around together, including periodically stopping and switching seating positions. They found that "contamination did not occur from riding in vehicles with contaminated people."

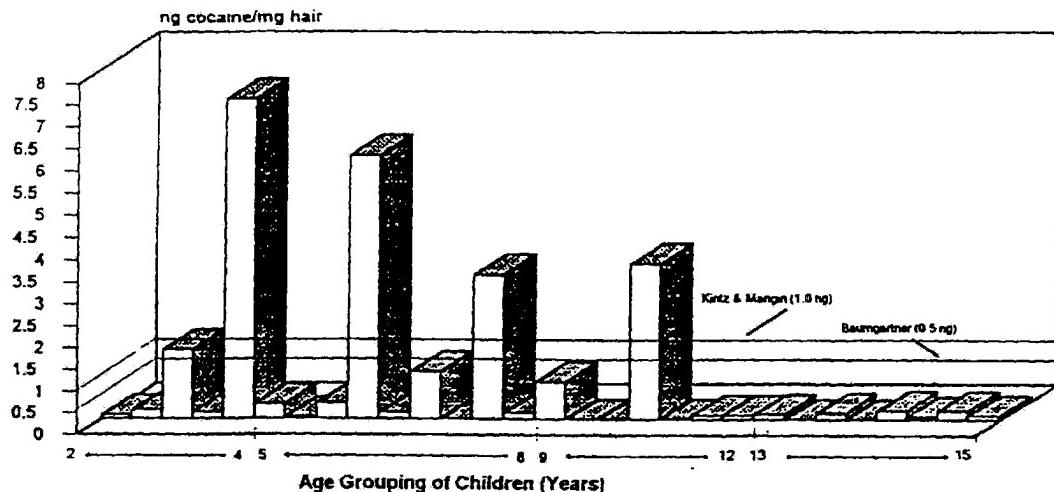
Contamination of Children Exposed to Cocaine

Smith, Kidwell, and Cook (1994: 1994a) have reported on a field study of the cocaine contamination of the hair of children of cocaine smokers. Several of these children, presumably residing primarily in the parental household, were characterized as having hair assay values indistinguishable from their cocaine-using parents. The study reported on 20 adult, cocaine-using parents and 29 associated children. Sixteen of the 20 adults and 29 of the children were reported as cocaine positive by hair analysis. They authors concluded that :

"These results show that cocaine-related compounds were deposited in the hair of children when cocaine was present in the environment. Children living with a cocaine dependent adult exhibited both cocaine and cocaine metabolite in their hair... If one assumes that young children are not intentional cocaine users and are not intentionally given cocaine by adults, these results show that their hair can become cocaine positive through unknowing exposure when they live with a cocaine user. Saliva and skin swabs suggest that external contamination, not ingestion (emphasis original), was the source of cocaine-related substances in the children's hair. Neither wash-out kinetics, metabolites, cut-off concentrations, nor re-test would exclude many of the children, presumed to be innocent non-users of cocaine, from being identified as cocaine users."

Figure 2 below, reproduces the outcomes for the 29 children and infants. Smith et al. reported these 29 cases as cocaine positive including 5 cases at levels below quantification (which they refer to as "trace" positives). These trace positive cases are indicated by the five bars which have no vertical dimension in Figure 2.

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**Figure 2. Children Reported as Cocaine Positive by Smith et al. (1994)**

Smith et al. conclude that "cut-off concentrations" would not exclude "many of the children" but this statement is not consistent with the data. In Figure 2 there are two cutoff criteria superimposed on the graph, indicated by the lines marked "Kintz and Mangin (1.0 ng)" and "Baumgartner (0.5 ng)." These represent two cut-off values for cocaine suggested in the literature. As each criterion line indicates, few of the children would be positive by either threshold criteria. Applying the 0.5 ng cutoff suggested by Baumgartner and Hill, only 7 of these 29 children would be classified as cocaine positive. Using the Kintz and Mangin "stand-alone" criteria of 1.0 ng, only 5 children would be positive.

The authors further state that the wash-out kinetics as developed by Baumgartner and Hill would not identify these children as "contaminated". Unfortunately, they do not provide the complete wash data. However, based on their description the Baumgartner and Hill criteria are not applied appropriately in this study. There were major modifications to the wash method as described by Baumgartner and Hill and there is only a single criterion used. The wash kinetic procedure alluded to in the study requires all three criteria to be met simultaneously. Furthermore, they do not utilize a digestion method on the post-wash hair. The Baumgartner and Hill protocol specifically states that:

"It is also important to realize that the presently defined kinetic criteria (particularly the numerical values) are only valid if the residual drug in the hair fiber is measured by a method that guarantees the complete release of the entrapped drug, e.g., a digestion procedure." (Baumgartner and Hill 1992)

Smith et al. also make direct comparisons between the assay values of the adults and children, noting that "in some cases the child's hair contained quantities

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greater than the adult user's hair." Without providing concentrations relative to body weight, these comparisons are difficult to assess, since they could result from the children chronically consuming very small dosages, given their much lower body mass. The pattern in Figure 2, indicating that the smallest children have the highest cocaine values, is a finding consistent with a hypothesized passive ingestion of small quantities of drugs, likely to be most pronounced in infants who are very orally active and who have very low body weights compared to other youths and adults in the sample. The data in Figure 2 is also consistent with the risk and quantity of ingestion lessening as a child age and matures. Aging would result in a decrease of the constant oral exploration and crawling activity of infancy. As well it would increase time spent outside the home, and increase the likelihood of eating food prepared out of the home environment (e.g., school cafeteria lunches). Figure 2 may also be demonstrating another aging effect, that the impact of passive ingestion would also be lessened, given a constant rate of exposure, by increasing body weight due to growth.

Smith et al., however, reject passive ingestion as a potential basis for explaining their findings, stating that "there is no evidence to support the hypothesis that ingestion was the primary route of cocaine entering hair." They base this statement on the results of saliva analysis for cocaine, which was negative for most of the children and many of the adults, and skin swabs, which were positive for every subject in the study. This, they argue, indicates that all subjects had been passively exposed to cocaine.

It does not appear that the ruling out of passive ingestion can be made on the basis of this data. Skin swab data, while it may indicate passive contamination, is also compatible with the sweat excretion of ingested cocaine. The method by which the authors differentiate cocaine found on the skin (from passive deposition) versus cocaine found on the skin as a result of sweat (or sebum excretion) is not elaborated. It is a plausible explanation that these children continuously ingested small amounts of cocaine over a long period of time via actions such as the placing of their hands or contaminated objects in their mouths, and continuously living in an environment in which their foodstuffs, eating utensils, play items, clothing, etc. are grossly contaminated by cocaine vapor. Certainly if the subjects themselves are contaminated, as the authors emphasize, it must also be true that their physical environment is contaminated as well. Two children, for example, are reported as having positive saliva assays, indicating possible recent ingestion of cocaine, or placement cocaine-contaminated objects into their mouths. Adults cracker users, who constitute the parent group, typically "cook up" or "rock up" cocaine in microwave ovens, often using ordinary household utensils (Mieczkowski 1992). The assessment of the degree of potential passive ingestion versus contamination would be strengthened by an evaluation of the degree of environmental contamination of the households and the clothing, eating utensils, foodstuffs, and play items of the children.

The interpretation of Smith et al.'s hair assay data is further complicated because hair samples collected for this study were taken in the course of a cosmetic styling of the hair. Such a collection process would presumably involve only the most distal ends of the hair shaft. During the course of the trim, the subject's hair was

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allowed to fall into a collection bag, producing a random mix of hair lengths, loci, and hair shaft orientations. Such a procedure would randomly mix hairs of varying lengths, and would fail to preserve root-to-distal end shaft orientation, make any longitudinal analysis or comparison of hair assay data to other drug use indicators impossible. Thus long-term interpretations of the outcomes of the hair assays relative to either saliva or urine assays - short-term measures - cannot be made. Also, this sample collection method is, unfortunately, not comparable to any other reported field studies, which have collected hair samples specifically cut from the scalp, and preserved them in proper orientation for the purposes of sectioning and comparison to urine tests and self-reports of drug use (See, for example, Marques, Tippetts, Branch 1993).

Narcotics Officers: Field Exposure to Cocaine

Field studies of naturally-occurring cocaine exposure are not easy to conduct. Because cocaine is a controlled substance with extremely limited medical use, it is difficult to identify occupational groups which have meaningful, known, and chronic environmental exposure to cocaine. However, one such group consists primarily of undercover narcotics officers and evidence custodians who manage the inventory of seized drugs. These individuals, in the course of their duties, have continuing contact with cocaine, cocaine-rich environments, cocaine users, and cocaine dealers. The officers function in environments where cocaine is consumed, they handle cocaine in the process of buying and selling it, they intimately handle cocaine during covert penetrations of drug selling organizations, when they make arrests and seize the associated contraband, and they transport and process the seized drug as part of the securing of the chain of evidence. Some of these officers also routinely handle cocaine as part of training exercises. Considering these factors, narcotics officers would appear to be a good study group for evaluating the degree of contamination acquired via incidental environmental exposure and, as well, the resistance of contamination to wash-based cleaning procedures. Certainly their exposure to cocaine far exceeds that which is likely to be incurred by the general public.

It is important to recognize that these officers often play covert roles as drug users and drug dealers. The narcotics control strategies they pursue includes posing as drug users, and convincing illegal drug sellers that they are "customers", i.e., drug users themselves. This precludes their ability to take precautions against contamination as that would have meaning in any ordinary laboratory setting. They cannot wear gloves or masks, etc. as this would betray their attempts to pass as drug users. These officers, in other circumstances (such as handling evidence once it is in police custody) may employ the conventional prophylactic measure of using gloves.

Based on the exposure these persons have to cocaine, and assuming none of these persons consciously abuse cocaine, a series of simple hypotheses are suggested:

1. It is hypothesize that the individuals in this sample are exposed to detectable levels of cocaine via environmental contamination. This contamination can be detected in

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the hair.

2. If their environmental contact and contamination results in micro-ingestion which emulates consumption characteristically seen in abusers of cocaine, these persons should have significant amounts of cocaine in their hair, after the hair is cleansed and tested. These amounts should be comparable to the values associated with self-admitted users of cocaine.
3. If they do have cocaine on or in their hair, but they are not similar in profile to willful consumers of cocaine, the wash procedures and ratio criteria designed to detect contamination as opposed to ingestion should identify these officers as contaminated non-ingesters of cocaine.

This study presents data based on the analysis of hair samples and responses to survey questions of 40 persons, 36 narcotics officers drawn from a number of police departments situated in a major metropolitan area of the southeastern United States, and 4 evidence room clerks who handle cocaine on a routine basis. Six challenge samples were also sent to the testing laboratory, which was unaware of their use in the study. Four officers were sampled twice, separated by approximately a four month interval¹. One office (case 19) did not complete a questionnaire. Thus there was a total of 50 samples analyzed for this project including 6 challenge samples. Thirty-nine questionnaires out of a possible 40 were completed. The participating officers and evidence clerks are employed as part of a county-wide, multi-departmental narcotics enforcement task force. These officers volunteered to provide a scalp hair specimen and answer a 24 item questionnaire on their undercover experience, their perceived exposure to cocaine, and their hair hygiene habits. The hair samples were gathered by 2 narcotics officers, who also administered the survey. All specimens and survey instruments were anonymous. Samples and surveys were common-coded to allow comparison of responses to values determined by assay of the hair specimen.

The hair was analyzed for cocaine by the Psychededics Corporation, of Culver City, CA., using radioimmunoassay and the preparatory method described by Baumgartner and Hill (1992). All positive cases were confirmed with GC/MS. The hair samples ranged from 1 to 4 cms. in length, and consisted of 20 to 40 strands of hair, cut at the scalp by surgical scissors. The hair was preserved with the root to distal orientation maintained. The hair was subject to an initial anhydrous isopropanol wash, and three subsequent phosphate buffer washes. After the third washing in buffer, the hair was digested by a proteinase enzyme at a neutral pH. Each wash and final hair digest was assayed by RIA. Complete technical description of the Psychededics sample preparation and assessment, and confirmation procedure has been published elsewhere (Baumgartner, Cawing, Donahue, Hayes, Hill, Scholtz, 1995). The criteria required to consider a sample cocaine positive are discussed in detail in Baumgartner and Hill (1992: 1995). The laboratory values are reported units of ng/mg. The data reported here included values for three phosphate buffer [PO₄] washes as well as the RIA values for the final hair digest.

¹ The duplicate samples were as follows: cases 4 & 10, 1 & 14, 6 & 15, 2 & 18.

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As part of a laboratory challenge component, the field samples sent to the laboratory also contained two positive contamination samples, which were fortified by aqueous soaks in cocaine (24 hours in 0.01mg/ml cocaine HCL) per the method of Wang and Cone (1995), three negative blanks, and one hair sample from a self-admitted, chronic crack cocaine smoker. The laboratory identified all challenge samples correctly.

There were 39 completed survey questionnaires. Table 2 presents basic descriptive information on the officers and their level of experience.

Table 2. Narcotics Officer, Descriptive Data (N=39)

Age (Mean)	36.0 years
Gender	
Male	33
Female	6
Ethnicity	
White	31
Black	4
Hispanic	4
Experience (Mean)	
Years in Narcotics	4.64
Years in Undercover	4.56

Reports of Exposure

The officer reported relatively frequent handling of cocaine. Almost all (97.3%) reported handling cocaine during purchases and arrests, and every officer (100%) reported handling contaminated objects when making purchases and arrests. Fifty-six percent handled cocaine several times weekly or more frequently. Table 3, below, reports frequencies for handling.

Table 3. Frequency of Handling Cocaine

How Frequently Do You Handle Cocaine?	
Daily or Near Daily	5 (12.8%)
Several Times Weekly	17 (43.6%)
Several Times Monthly	14 (35.9%)
Rarely	3 (7.7%)

The majority of the cases handled by these officers were cocaine cases (mean value 65.9%; range from 2 to 100%). And the majority of the cocaine cases were crack cases as opposed to powder cocaine cases (mean value 60.1%; range from 0 to 100%). Nearly all officers (97.3%) reported consistent and ongoing activities relative to cocaine, which included handling, purchasing, seizing, field testing, and transporting cocaine. The handling of crack cocaine by many of these officers included intense,

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unprotected contact. Examples of this kind of contact included "tongue tasting" (the touching of one fingers to cocaine and the subsequent touching of the tongue) and "bumping." Bumping is a form of tipping. When one purchases cocaine via an introduction through an intermediary, it is customary to smoke some of the crack with the intermediary as a gratuity. Since these officers cannot smoke crack, they alternatively give a "bump" as a gratuity. This is usually done by the officer crumbling or breaking of a piece of the "rock" with their fingernail, and giving the fragment to the intermediary.

As Table 3 indicates, these officers have frequent contact with cocaine. Many also spend significant time in social settings with persons who use cocaine, who use cocaine in their presence, and periodically attempt to induce them to use cocaine. Table 4 reports the counts of contact type as reported by the officers.

Table 4. Number of Officers Reporting Types of Cocaine Contacts

Frequency of Contact	Present Around Powder Cocaine	Present When Crack is Smoked	Present in Environment Where Crack is Smoked
Daily	4	1	1
Several Times Weekly	8	3	6
Weekly	2	2	2
Several Times Monthly	7	4	9
Monthly	4	4	5
Less Than Monthly	12	19	10
Never	2	6	6

The officers were also requested to self-estimate their own level of exposure. In Table 5 the officers' views on their degree of exposure are presented.

Table 5. Officers' Self-Estimates of Exposure to Cocaine

Degree of Perceived Exposure	Number of Officers (%)
non-existent	4 (10.3)
slight	13 (33.3)
moderate	14 (35.9)
heavy	6 (15.4)
extreme	2 (5.1)

More than half of these officers estimate their exposure to be from moderate to extreme. Although 64% report that they use some form of precautions (typically wearing rubber gloves) when handling cocaine, these measures are only employed in two circumstances. One is during the execution of some search warrants, and second during the transferring of cocaine within the department after it has been seized and

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taken into custody. More than 1/3 of the officers report that they use precautions under any circumstances. None of the officers, of course, use gloves or masks when making covert buys in the field.

Hair Hygiene and Cosmetic Treatment

It is generally recognized that the washing and cosmetic manipulation of hair affects both its capacity of absorb and shed drugs and other materials it acquires from the environment. Examining the hair treatment practices of the sample revealed no notable departure from what one might perceive as normal washing patterns. Table 6 reports the frequency of hair washing by the officers.

Table 6. Frequency of Hair Washing

Frequency of Hair Washing . . .	Number of Officers (%)
More than Daily	2 (5.3)
Daily	31 (81.6)
3-5 Times Weekly	4 (10.5)
Once Weekly	1 (2.6)

As Table 6 indicates, daily washing of hair is clearly the modal practice. Other aspects of hair hygiene and cosmetic treatment are presented in Table 7.

Table 7. Shampooing and Cosmetic Treatment of Hair

Do you use . . .	Yes	No
A Regular Commercial Shampoo?	38	1
A Creme Rinse?	23	16
Do You . . .		
Cosmetically Treat Your Hair?	11	28

The types of cosmetic reported by the officers consisted primarily of "perms" (7), followed by the use of hair sprays, gels, and mousses (2), with a single report each of dyeing and bleaching of the hair. Of the 7 perms reported by the officers, 4 were reported by males and 3 by females. Since the study was retrospective, there was no concern with efforts on the part of officers to either avoid or engage in special hair treatment or hygiene which would affect the assays procedure.

Hair Analysis Data

Table 8 displays the data outcome for the hair assays for cocaine for all subjects in the study. Samples for these cases represent approximately 90 days of retrospection - roughly 3.9 cms. In length. Examination of the table reveals that every officer had some measurable amount of detectable cocaine on their hair, with the exception of two

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cases which had a zero value for every wash and the digest. One sample, #27A, attained sufficient value for cocaine (0.52 ng/mg) to be considered a positive assay by the 0.5 ng/mg cutoff. A repeat sample (designated #27B in Table 8) was obtained from the subject. This sample was, on subsequent analysis, negative. The second sample, however, was not comparable in time sequence to the first, because a 4 month interval had elapsed. Given the circumstances of this case, it is quite possible that the first sample outcome represents passive ingestion of cocaine, since this sample met all wash and metabolite criteria. Only one other sample, #26 (which was obtained from an evidence technician of approximately 60 years of age), had a measurable amount of cocaine in the digest, 0.072 ng/mg, a value well below the cutoff. All other samples had zero values for the digest. The alcohol wash values are dominated by zero outcomes (35 samples), with 9 cases having values above zero. The mean value for the alcohol wash for the group as a whole is 0.006 ng/mg. The mean value for the series of phosphate buffer washes are as follows: first PO₄ wash, 0.0531 ng/mg; second PO₄ wash, 0.0049 ng/mg; third PO₄ wash, 0.0010 ng/mg. In each cases the series of PO₄ washes shows that in each subsequent wash step the concentration value was lowered, or reduced to zero. While 42 of the 44 samples has a value greater than zero in the first PO₄ wash, only 18 cases had cocaine in the second PO₄ wash, and only 4 cases had any cocaine remaining in the third wash.

(Table 8 on following page)

Control and Fortified Samples

Table 9, below, presents data for the 3 negative control samples, 2 "spiked" or fortified samples, and a sample submitted collected from a self-reported crack smoker.

Table 9. Assay Outcomes for Negative and Positive Control Samples [ng/mg]

Case ID#	Sample Type	Alcohol Wash	PO ₄ #1	Buffer #2	Washes #3	Hair Digest
42	Negative	.018	.008	0	0	0
43	Spiked	46.7	146.0	38.0	34.8	296.4
44	Negative	.014	0	0	0	0
45	Spiked	26.6	53.3	17.8	8.9	103.6
46	Negative	.008	.017	.006	0	0
47	S/R user	2.1	5.5	2.5	2.0	214

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Discussion

Based on the data presented here several observations may reasonably be made in reference to the suggested hypotheses.

The first hypothesis is consistent with the findings reported here. These persons are exposed to cocaine in the course of their work, and such exposure generally results in the environmental contamination of their hair. This contamination is detectable by RIA. The levels of the detected contamination are comparable to the amount of contamination reported by other *in vivo* contamination experiments. The values for the officers in this study are, for example, very close to the background contamination values reported by Koren et al. for persons never reporting any cocaine use.

Second, it appears that although these officers are chronically exposed to cocaine through their work, their exposure as measured by hair analysis is slight. If they are also micro-ingesting cocaine, it is at a level so low as to clearly distinguish them from cocaine users. However, as described in this paper, contamination must always be considered as an aspect of assay interpretation. The findings related to case 27 serve as a reminder that intense exposure to cocaine may lead to contamination via microingestion. Bear in mind some officer in this study reported field practices which would lead directly and indirectly to oral contamination. Such techniques as "tongue tasting" or "bumping" must be considered when interpreting a low level positive, which is near the cutoff.

Third, it appears as a consequence of these findings that the alcohol and phosphate buffer wash procedure are an adequate method for removing external contamination from hair, at least for the type of exposure experienced by these individuals. Thus our data supports the findings of Koren et al., and others who have argued that environmental contamination is not an insurmountable problem to the interpretation of hair assays under most normal circumstances where contamination is likely to occur.

This study also indicates that passive contamination of hair specimens as practiced in laboratory scenarios, at least based on the *in vitro* contamination processes reported to date, are not likely to be accurate reflections of "real world" contamination for many groups of interest in criminal justice practice. Laboratory studies exposing hair to aqueous cocaine soaks or pyrolyzed cocaine vapors have reported contamination at concentrations many orders of magnitude greater than what appear in this field. More intensive study of field populations and determining background levels of exposure for the purposes of developing interpretive guidelines is probably a far more useful approach to the issue of cutoff determination than synthetic laboratory contamination approaches.

The results of this study, especially when considered in light of the findings of Maloney et al., Ulwick et al., Demirgian et al., and Koren et al., encourage an approach to studying contamination problems in real-world environments. It is apparent that to

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accurately gauge the likelihood of misinterpretation of assays based on contamination as opposed to ingestion, background values need to be empirically determined in field settings. It is a reasonable conjecture that establishment of these field-based parameters would likely show that for most routine situations, wash procedures and sample preparation techniques similar to those used in this study are adequate safeguards against confusing contamination with meaningful cocaine ingestion.

Surely there are going to be extraordinary cases when a person is significantly contaminated with cocaine. Perhaps, for example, by deliberate sabotage, through the deliberate "spiking" of food. It may also be possible that with chronic, intimate skin-to-skin contact, augmented by exchange of body fluids through sexual activity that an "innocent" person becomes contaminated via contact and ingestion and could attain sufficient concentration in the hair to cross the lowest threshold as an evidentiary positive. Persons (such as undercover narcotics officers) who are peripheral but chronically "dabble" with cocaine may be detected as positive at low values. This may also be true for persons who sell or package cocaine, but do not regularly or recreationally use the drug in any active manner. However, there is little in the way of data to support this as a commonplace event, and considerable data to support the view that such events are rare. It seems implausible that such persons could attain the values we consistently find in active cocaine users.

The criticism made that a distinction between contamination and use is a "fatal flaw" for hair analysis does not appear to be viable. In many criminal justice situations the difference between exposure and use is a moot issue in any event. Furthermore, there is always going to be some degree of environmental contamination when a person is using cocaine, and there is always some level of microingestion when a person is contaminated with measurable quantities of cocaine. Indeed, the same condition is true for urine-based testing, and is the raison d'etre that cutoff values for assays exist. The same logic is applicable to hair analysis. While there may be some contention about precisely where those cutoffs ought to be placed, there does not appear to be evidence which indicates that a reasonable cutoff threshold is unattainable or would work any less efficiently and effectively than it works for urine, or plasma, or any other matrix used to test for drugs.

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Mieczkowski. "Distinguishing Passive Exposure"

Abstract

Hair analysis has been used in probationary and parole populations to monitor for cocaine use, but only in very limited settings or circumstances. Its wider adoption has been limited by questions regarding the ability to distinguish environmental contamination of hair via casual contact from actual ingestion. To evaluate this capability we sought to identify persons routinely exposed to cocaine, who were not cocaine users. Undercover narcotics officers engaged in cocaine-centered enforcement activities and evidence room clerks who have no history of cocaine use were identified as an appropriate example population. 36 active undercover officers and 4 evidence technicians were asked to voluntarily submit hair samples for analysis. Additionally two cocaine contaminated (aqueous soaked), three negative control samples, and hair from a self-reported crack smoker were also blindly submitted to the testing laboratory. The hair samples were washed and after washing, enzyme digested. The wash solutions and hair digest were each analyzed for the presence of cocaine. The results indicate that nearly every person had trace amounts of cocaine contamination in the wash fraction, and one person had cocaine present in their hair digest. That person, when retested, was a negative. The laboratory correctly identified and characterized the contaminated, negative, and positive controls. The study concludes that the findings support the capability of hair analysis to distinguish cocaine use from exposure under normal field conditions. The study results indicate that cocaine-abstinent persons who are in chronic, casual environmental contact with cocaine are not likely to test hair positive for cocaine using the analysis protocols followed in this project. The study also indicates that passive microingestion of cocaine needs to be considered when examining persons who are in cocaine intensive environments.

Mieczkowski, "Distinguishing Passive Exposure

Sample #	Alcohol Wash	PO ₄ #1	Buffer #2	Washes #3	Hair Digest
1	.09	.13	.014	0	0
2	0	.10	.01	0	0
3	0	.15	.014	0	0
4	0	.34	.03	.02	0
5	0	.08	.008	0	0
6	.11	.12	0	0	0
7	0	.34	.01	.01	0
8 ²	0	.11	.007	0	0
9	0	.15	.018	0	0
10	0	.05	0	0	0
11	0	.03	0	0	0
12	0	.01	.01	0	0
13	0	.06	.01	0	0
14	0	.07	.01	0	0
15	0	.04	.01	0	0
16	0	.01	.01	0	0
17	0	.10	.01	0	0
18	.01	.02	0	0	0
19	0	.04	0	0	0
20	0	.05	0	0	0
21	0	.06	0	0	0
22	0	.05	0	0	0
23	.004	.30	0	0	0
24	0	.004	0	0	0
25 ²	0	.008	0	0	0
26 ²	.002	.018	.009	.003	.072
27A	.006	.03	.019	.016	.52
27B ³	0	0	0	0	0
28	0	.004	0	0	0
29	0	.005	0	0	0
30	0	.008	0	0	0
31	0	.007	0	0	0
32	0	.013	0	0	0
33	0	.013	0	0	0
34	0	.008	0	0	0
35	0	.011	0	0	0
36	0	.02	0	0	0
37	0	.007	0	0	0
38	0	.008	0	0	0
39 ²	0	.008	0	0	0
40	.011	.007	0	0	0
41	0	0	0	0	0
48	.020	.021	.007	0	0
49	0	.010	.005	0	0
50	.011	.018	0	0	0

Table 8. Wash and Hair Digest Assay Values: Cocaine [ng/mg]

²These cases are evidence clerks.³This represents the of a second sample on case 27 which to a later time frame. The first sample was, as indicated, slightly above the cutoff threshold .

Exhibit 8

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1 (Document marked as Devlin
 2 Exhibit 8 for identification)
 3 Q. Have you had an opportunity to review what
 4 has been marked as Exhibit 8?
 5 A. Yes.
 6 Q. Is this one of the documents you reviewed
 7 in preparation for your testimony today?
 8 A. Yes.
 9 Q. I will describe it briefly for the record.
 10 It is a four-page document marked COB 6244 through
 11 6247. If you look at Page 6244, have you ever seen
 12 this page of the document before?
 13 A. No.
 14 Q. Look at Pages 6245 through 6247. Other
 15 than in preparation for your testimony today, have
 16 you seen this document before?
 17 A. I wrote it.
 18 Q. 6244 does reference a weekly meeting. It
 19 says, "To be discussed at next weekly meeting." Do
 20 you recall discussing 6245 through 6247 at a weekly
 21 meeting?
 22 A. I was not invited to that weekly meeting.
 23 Q. Did you know that there was a weekly
 24 meeting, whether or not there was a weekly meeting

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1 own airfare and hotel.
 2 Q. Did you have to justify the expenditure for
 3 the symposium fee to anyone?
 4 MS. HARRIS: Objection. You can answer.
 5 A. No, I asked. There wasn't enough money
 6 for them to pay airfare and hotels, so they only
 7 paid the symposium fee.
 8 Q. Were you asked to attend the symposium?
 9 A. No.
 10 Q. How did you find out about it?
 11 A. I had attended a previous one. I was on
 12 the mailing list.
 13 Q. One previous?
 14 A. Yes.
 15 Q. Did the previous AAMRO meeting that you
 16 attended concern drug testing in any way, shape, or
 17 form?
 18 A. Yes.
 19 Q. Did it concern hair testing?
 20 A. I really don't remember. It was two years
 21 prior.
 22 Q. Did you draft a memorandum for the prior
 23 AAMRO meeting that you attended?
 24 A. No. Not that I recall, anyway.

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1 to discuss the documents set forth in 6245 through
 2 6247?
 3 A. I don't know what weekly meeting it would
 4 have been at, whether it would have been a meeting
 5 chaired by Deputy Superintendent O'Malley or just
 6 one that she was attending. I have no idea.
 7 Q. Did you ever discuss the memorandum that
 8 you prepared, 6245 through 6247, with anyone?
 9 A. No.
 10 Q. The first paragraph of the December 11,
 11 2003, memorandum says, "The American Association of
 12 Medical Review Officers (AAMRO) Annual Drug Testing
 13 Symposium held from December 5 through 7, 2003,
 14 covered many areas, but several were of particular
 15 interest." Did you attend the symposium?
 16 A. I did.
 17 Q. Where was it?
 18 A. Las Vegas.
 19 Q. Did anyone else from the Police Department
 20 attend?
 21 A. No.
 22 Q. Did the Police Department pay your expenses
 23 for attending the symposium?
 24 A. They paid me the symposium fee. I paid my

1 Q. Did anyone ask you to draft this
 2 memorandum?
 3 A. No.
 4 Q. Why did you draft it?
 5 A. Let them know what they got for their
 6 money.
 7 Q. Did you talk to anyone at the Police
 8 Department about what you learned at the AAMRO
 9 meeting? Other than setting forth in the memorandum
 10 here, did you talk to anyone?
 11 A. Not that I recall, no.
 12 Q. If you look at second page, there's a
 13 section here called "Hair Testing." The first
 14 paragraph states, "John Irving, Laboratory Director
 15 for Sure Test Laboratories (and the former Assistant
 16 Laboratory Director for Psychemedics) gave a
 17 presentation that detailed the testing process for
 18 drug hair tests done by Psychemedics. His
 19 presentation was very thorough and covered every
 20 facet of the drug hair test process, including the
 21 collection of the sample, the hair washing
 22 procedures and the type of both the initial and
 23 confirmatory tests done, i.e., RIAH, GC/MS, GC/MS/MS
 24 and LC/MS." Did I read that correctly?

1 A. Yes.
 2 Q. Other than attending this symposium, were
 3 you familiar with Psychededics' washing procedures?
 4 A. No.
 5 Q. Other than you from drafting this
 6 memorandum, is there anyone else at the Police
 7 Department who is familiar with Psychededics'
 8 washing procedures?
 9 A. I have no idea.
 10 Q. If you would take a moment to review the
 11 next two paragraphs.
 12 A. (Reviewing document)
 13 Q. I will just read the second of the two
 14 paragraphs if you have had an opportunity to look at
 15 the first one. For the record, it says, "However,
 16 in my opinion, Dr. Caplan presented a very
 17 misleading and factually erroneous presentation to
 18 an entire room full of Medical Review Officers when
 19 his portion of the lecture covered the topic of
 20 allegations of racial bias in hair testing. Dr.
 21 Caplan's presentation nurtured the belief that hair
 22 testing is potentially racially biased while
 23 presenting evidence that clearly shows no such thing
 24 and at most suggested a potential only for 'hair

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1 have a slightly higher retention rate than
 2 light-colored hair, but that's not racial. It's
 3 hair color. And he presented no evidence that it
 4 was racial, that I recall.
 5 Q. When you say "hair color," are you
 6 referring to natural hair color?
 7 MS. HARRIS: Objection. Go ahead.
 8 A. Yes.
 9 Q. So going back to the question I asked
 10 before, you said it would depend on what the extent
 11 of the hair color bias was whether or not you would
 12 be concerned that the Police Department was using
 13 the hair test. What did you mean by that?
 14 MS. HARRIS: Objection. You can answer.
 15 A. If there was a very slight bias that, for
 16 instance, dark hair had a greater retention period
 17 than light-colored hair, well, I am not going to be
 18 that concerned because we are still talking about
 19 people who have used a controlled substance in
 20 violation of the rule and in violation of the law.
 21 So I don't have that much sympathy. But
 22 nevertheless, you do want any differences to be no
 23 more than minor variances.
 24 Q. Did Dr. Caplan at this meeting talk about

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 1 color bias.' Additionally, he totally glossed over
 2 any evidence that indicated that such a bias did not
 3 exist." It finishes off with a question, "Why?"
 4 Would you have had concerns about the
 5 Police Department's use of the hair test if there
 6 was a hair color bias?
 7 MS. HARRIS: Objection. You can answer.
 8 A. I'm sorry. Could I have the question
 9 again.
 10 Q. Would you have concerns about the Police
 11 Department's use of the hair test if there was a
 12 hair color bias?
 13 MS. HARRIS: Objection. You can answer.
 14 A. I guess it would depend on the extent.
 15 Q. What do you mean by that?
 16 MS. HARRIS: Objection.
 17 A. What do you mean by "hair color bias"?
 18 Q. Let me ask you. What do you mean by "hair
 19 color bias" when you wrote it in your memo?
 20 MS. HARRIS: Objection.
 21 A. Bearing in mind I wrote this memo three and
 22 a half years ago, I believe that the only evidence
 23 that Dr. Caplan had presented might have indicated
 24 that the color of a person's hair might potentially

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 1 the ability of various hair tests, whatever hair
 2 test he was discussing, to eliminate external
 3 contamination as the source of a positive test
 4 result?
 5 A. I really don't remember.
 6 Q. Turn to the next page. The first paragraph
 7 states -- I will just read it for the record -- "One
 8 individual who was not at the conference is Dr.
 9 Thomas Mieczkowski." M-i-e-c-z-k-o-w-s-k-i. "Dr.
 10 Mieczkowski is a professor in the Department of
 11 Criminology at the University of South Florida.
 12 Unlike those presenters who previously or currently
 13 work for laboratories and/or consulting firms, Dr.
 14 Mieczkowski is a professor and researcher who has
 15 analyzed past studies conducted on hair drug testing
 16 as well as having conducted studies of his own (see
 17 attached copies of studies and/or abstracts). His
 18 findings conclude that any evidence of racial or
 19 hair color bias is either statistically
 20 insignificant or is no greater than statistical
 21 variances that exist within racial or ethnic groups.
 22 Lending further credence to the results of his
 23 research, Dr. Mieczkowski has conducted several
 24 large-scale studies (one of which included over

1 56,000 subjects) instead of the poorly designed,
 2 small-scale studies that are frequently cited by
 3 others to discredit the reliability of hair
 4 testing."

5 On what basis did you determine that the
 6 other studies were poorly designed small-scale
 7 studies?

8 MS. HARRIS: Objection. You can answer.
 9 A. An article that Dr. Mieczkowski had
 10 written.

11 Q. From the second sentence of the paragraph
 12 that I just read, I take it it was important to you
 13 that you thought Dr. Mieczkowski was independent
 14 from any laboratory or consulting firm; is that
 15 correct?

16 MS. HARRIS: Objection. You can answer.
 17 A. In my eyes, it gave him more credibility,
 18 yes.

19 Q. And you thought he was independent, for
 20 example, from Psychemedics?

21 MS. HARRIS: Objection. You can answer.
 22 A. I hadn't really thought about it.

23 Q. You state here that he was independent,
 24 correct, from laboratories or consulting firms?

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1 curriculum vitae was publicly available on the
 2 University of South Florida's Web site?

3 A. I don't know.
 4 (Document marked as Devlin
 5 Exhibit 9 for identification)

6 Q. I have had marked as Devlin 9 Thomas
 7 Mieczkowski's curriculum vitae. I will represent to
 8 you that this was printed off the University of
 9 South Florida's Web site. I take it you have never
 10 seen this document before?

11 A. That's correct.

12 Q. If you flip forward to Page 8, there's a
 13 section here in the middle of the page, "Contracts
 14 Or Grants Received." Just flip back a page there.
 15 Do you see that?

16 A. I do.

17 Q. Do you see that the second grant listed
 18 says, "The Psychomedics Corporation, Principal
 19 Investigator, Sabbatical Research Fellowship"?

20 A. I do.

21 Q. Did you know that Dr. Mieczkowski had
 22 received a grant from Psychomedics in 2000 for the
 23 2000 to 2001 academic year?

24 A. No.

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1 A. As far as I knew.

2 Q. So that would include Psychomedics?

3 A. I did not know of any association that he
 4 may or may not have had with Psychomedics, if that
 5 answered your question.

6 Q. If you did know he had an association with
 7 Psychomedics, would that have changed the views you
 8 expressed here in this paragraph?

9 A. Not necessarily.

10 Q. If it turned out, for example, that Dr.
 11 Mieczkowski's work was funded by Psychomedics, would
 12 you doubt the findings that are made here that he
 13 was independent?

14 A. Not necessarily.

15 Q. You'd still consider him independent?

16 MS. HARRIS: Objection. Well, you can go
 17 ahead and answer it.

18 A. I would consider him to be less
 19 independent, but that wouldn't necessarily mean that
 20 I wouldn't believe his results.

21 Q. Did you ever check to see if your statement
 22 that Dr. Mieczkowski was independent was accurate?

23 A. No.

24 Q. Did you know that Dr. Mieczkowski's

1 Q. You didn't know that when you drafted your
 2 memo to your supervisors, did you?

3 A. No, I didn't.

4 Q. If you had known that, would you describe
 5 him as independent from laboratories?

6 MS. HARRIS: Objection. You can answer.

7 A. No, I probably would not have used that
 8 phrase.

9 Q. Flip two more pages in. Take a moment to
 10 look at that. According to this page, I see here
 11 that Dr. Mieczkowski traveled to Genoa, Italy, in
 12 1991, 1993 and 1995 to deliver a presentation. Do
 13 you see that?

14 A. I do.

15 Q. Who funded those trips for Dr. Mieczkowski
 16 to go to Genoa, Italy?

17 A. According to this document, Psychomedics.

18 Q. Would you have represented to your
 19 supervisors that Dr. Mieczkowski was independent in
 20 2003 if you had known this information?

21 A. I probably would have used different
 22 terminology.

23 Q. Turn to the next page. Do you see here
 24 where it says that Psychomedics paid for Dr.

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 1 Mieczkowski to travel to Martigny, Switzerland, on a
 2 travel grant in 1999?
 3 A. Yes, I do.
 4 Q. If you had known that, would you have
 5 represented that Dr. Mieczkowski was independent to
 6 your supervisors?
 7 A. Probably not.
 8 (Document marked as Devlin
 9 Exhibit 10 for identification)
 10 Q. I am not going to have a lot of questions
 11 on this. Would you take a moment to review it.
 12 A. (Reviewing document)
 13 Q. Just for the record, this is a document
 14 dated June 10, 1996. COB 7675 through 7702. It
 15 would appear to be a document called "Distinguishing
 16 Passive Contamination From Active Cocaine
 17 Consumption: Assessing the Occupational Exposure of
 18 Narcotics Officers to Cocaine." Again, it is dated
 19 June 10, 1996. It says at the bottom, "Presented at
 20 the 1st European Meeting on Hair Analysis, Clinical,
 21 Occupational, and Forensic Applications, Torre
 22 Cambiasso Center, Genoa (Pegli) Italy, June 17
 23 through 19, 1996." Then it says, "The author would
 24 like to acknowledge," et cetera. Is this the

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 1 C E R T I F I C A T E
 2 I, Joseph T. Devlin, Jr., do hereby certify that
 3 I have read the foregoing transcript of my
 4 testimony, and further certify under the pains and
 5 penalties of perjury that said transcript
 6 (with/without) suggested corrections is a true and
 7 accurate record of said testimony.
 8 Dated at _____, this ____ day of _____.
 9 2007.
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 11 _____
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 1 document that you referred to in Exhibit 8 as a copy
 2 of a study or abstract from Dr. Mieczkowski?
 3 A. No.
 4 Q. It was a different document?
 5 A. Yes.
 6 Q. Have you ever seen this document before?
 7 A. Not to my knowledge.
 8 MR. BAKER: I have no further questions.
 9 MS. HARRIS: Okay.
 10 (Whereupon, the deposition was
 11 concluded at 3:10 p.m.)
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 1 COMMONWEALTH OF MASSACHUSETTS)
 2 SUFFOLK, SS.)
 3 I, Daniel P. Wolfe, Registered Professional
 4 Reporter and Notary Public in and for the
 5 Commonwealth of Massachusetts, do hereby certify
 6 that there came before me on the 7th day of June,
 7 2007, at 12:45 p.m., the person hereinbefore named,
 8 who was by me duly sworn to testify to the truth and
 9 nothing but the truth of his knowledge touching and
 10 concerning the matters in controversy in this cause;
 11 that he was thereupon examined upon his oath, and
 12 his examination reduced to typewriting under my
 13 direction; and that the deposition is a true record
 14 of the testimony given by the witness.
 15 I further certify that I am neither attorney or
 16 counsel for, nor related to or employed by, any
 17 attorney or counsel employed by the parties hereto
 18 or financially interested in the action.
 19 In witness whereof, I have hereunto set my hand
 20 and affixed my notarial seal this ____ day of June,
 21 2007.
 22 _____
 23 Notary Public
 24 My commission expires 9/18/09

Exhibit 9

Q
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External Contamination of Hair with Cocaine: Evaluation of External Cocaine Contamination and Development of Performance-Testing Materials*

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Abstract

The National Laboratory Certification Program undertook an evaluation of the dynamics of external contamination of hair with cocaine (COC) while developing performance testing materials for Federal Drug-Free Workplace Programs. This characterization was necessary to develop performance materials that could evaluate the efficacy of hair testing industry's decontamination procedures. Hair locks (blonde to dark brown/black) from five different individuals were contaminated with cocaine HCl. Hair locks were then treated with a synthetic sweat solution and hygienic treatments to model real-life conditions. Hair locks were shampooed daily (Monday through Friday) for 10 weeks, and samples of the hair locks were analyzed for COC, benzoylecgonine (BE), cocaethylene (CE), and norcocaine (NCOC). Three commercial analytical laboratories analyzed samples under three protocols: no decontamination procedure, individual laboratory decontamination, or decontamination by an extended buffer procedure at RTI International. Results indicated substantial and persistent association of all four compounds with all hair types. Hair that was not decontaminated had significantly greater quantities of COC and BE than did hair that was decontaminated. The only hair samples below detection limits for all four compounds were those decontaminated 1 h after contamination. Additionally, BE/COC ratios increased significantly over the 10-week study (regardless of decontamination treatment). From 21 days postcontamination until the end of the study, the mean BE/COC ratio for all hair types exceeded 0.05, the proposed Federal Mandatory Guidelines requirement. The largest variability in results was observed for samples decontaminated by participant laboratories. This suggests that current laboratory decontamination strategies will increase variability of performance testing sample results. None of the decontamination strategies used in the study were effective at removing all contamination, and some of the contaminated hair in this study would have been reported as positive for cocaine use based on the proposed Federal Mandatory Guidelines.

Introduction

In 2000, RTI International was directed by the Division of Workplace Programs, Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS), to conduct a pilot hair performance testing (PT) under the National Laboratory Certification Program (NLCP). The purpose of this pilot was to develop quality assurance testing materials in support of anticipated changes in Federal Drug-Free Workplace testing programs. Initially, participating laboratories were directed to test the PT samples using their complete procedures including their decontamination wash procedures prior to confirmation. The large variability in the reported quantitative results required the program to limit procedural variables. The most obvious contributor to variability, individual laboratory decontamination procedures, was discontinued in favor of a uniform decontamination procedure as part of the manufacturing process. Further testing of samples has found continued variability in results both between and within laboratories, but this can no longer be attributed to differences between decontamination procedures (1). However, the need to assess the effectiveness of decontamination procedures continues to remain a PT objective. In RTI's efforts to refine and develop performance testing materials to assess laboratory performance, we have sought to evaluate the dynamics of external contamination to produce a means to test the efficacy of decontamination procedures.

For the past two decades, researchers and scientists have investigated and employed hair testing for drugs of abuse as a complementary and alternate matrix to blood and urine. Results from hair tests have been used in clinical, forensic, and epidemiological studies; historical research; and courts of law. Testing for drugs in hair has evolved to the point that the identity of the drug found is less of an issue than the explanation of its origin. The risk for environmental contamination alone to produce a positive drug hair test result is not clear.

All mechanisms by which drug is incorporated into hair are not fully understood. Drug incorporation into hair can occur

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[‡] RTI International is a trade name of Research Triangle Institute.

through blood exchange at the hair follicle; exposure to sweat and sebaceous secretions; transdermal diffusion of drug from the skin; and also from exposure to the external environment, including drug residues, contaminated surfaces, and vaporized drug (2–5). Each of these mechanisms is affected by the chemical and physiological composition of the hair matrix.

The functional groups (e.g., carboxyl and phenolic groups) of many hair proteins promote cation-exchange activity between the hair proteins and small ionic molecules such as drug (6). Hydrophobic and hydrophilic interactions between hair and drugs have been demonstrated *in vivo* (7). These interactions result in ionic bonding between hair and the retained drugs (8). Claffey and Ruth (9) and Dehn et al. (10), using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry, reported evidence of covalent adduct formation of amphetamine and nicotine/cotinine with melanin intermediates during *in vitro* melanogenesis. The relative contribution to drug retention in hair by each of these interactions is poorly defined.

The issue of environmental contamination is further confounded by evidence that incorporation rates of drugs vary in hair with different melanin and protein content (5,11). The relative proportion of melanin associated protein can vary as much as 40% (11). Similarly, Chinese black hair has an average melanin content of 3%, and Scandinavian blonde hair contains 0.07% melanin (12). Thus, it is possible that the amount of drug incorporated into hair, either by environmental contamination or ingestion may vary with the protein and melanin content further complicating the development of a clear understanding of a hair test result.

To minimize the impact of environmental contamination issues, laboratories have developed decontamination procedures to remove putative surface contaminants. A variety of decontamination schemes are used to remove potentially interfering substances such as lipids, oils, and cosmetics, as well as exogenous analytes (e.g., drug) possibly coating the hair surface from environmental exposure. Researchers have investigated organic solvents, aqueous buffers, water, soaps, and combinations of these for decontamination wash procedures (13). These procedures can take from minutes to hours to perform. The extent to which hair can be decontaminated

depends on factors governing penetration of the drug into the hair matrix such as cosmetic treatment of hair and the chemical and physical properties of the drug analyte (14–16).

Regardless of the decontamination procedure employed, the efficacy of decontamination washes is debatable. Some researchers believe a rapid aqueous or organic solvent wash is sufficient (13). Other investigators have proposed a multi-step decontamination procedure including a "wash kinetic criteria" to properly distinguish passive exposure and active ingestion of a drug by comparing drug in the wash fractions with the drug extracted from the hair matrix (17). Researchers who have demonstrated that drug residue remains associated with the hair even after extensive washing procedures have questioned the efficacy of wash procedures (18,19).

Several groups investigated the efficiency of removing cocaine (COC) from hair after external application. A review of the literature indicates that aggressive washing techniques can remove COC from hair 1 h after it has been applied to the hair either as a solution or as a powder (18,20). However, beyond an hour, one group reported wash procedures were unable to remove all of the COC in the hair up to 10 weeks post-application (18). Cairns et al. (17), utilized a solution of COC in chloroform to contaminate hair samples, arguing this more closely approximated surface contamination of hair. These investigators reported that following several shampoo wash-dry cycles, the external contamination could be differentiated by an extensive wash and application of a mathematical factor similar to that used in two previous publications. The article also stressed differences in the wash procedures utilized by their group and Romano et al. (18) as an explanation for why the results differed between the two groups.

Our laboratory investigated the issue of environmental contamination of hair with COC using a protocol similar to that of Cairns et al. (17) and Romano et al. (18). The hair samples were sent for analysis to three laboratories. Briefly, COC HCl was externally applied to different hair types and the concentrations of COC analytes determined over a 10-week period during which the hair was subjected to regular shampooing.

Experimental

Experimental design

The design of the experiment was as a three-way, crossed design, with sub-sampling. The factors investigated were time, hair-type, and decontamination protocol. Samples were removed at 14 time points with respect to contamination (pre-contamination, 1 h, 6 h, 27 h, weekly) during a 70-day period (Figure 1). Hair-type consisted of 5 hair locks of various colors and types (Table I). Decontamination protocols comprised three strategies: 1. no decontamination; 2. a decontamination by the analytical laboratory using the laboratory's standard protocol; and 3. a decontamination protocol at RTI prior to submission to analytical laboratories.

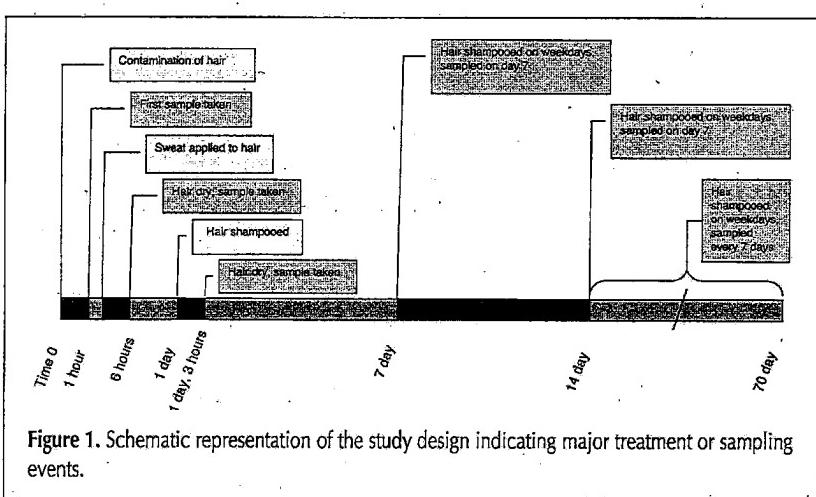


Figure 1. Schematic representation of the study design indicating major treatment or sampling events.

All hair types were contaminated with cocaine, subjected to a treatment with synthetic sweat after 1 h, and shampooed each weekday evening (Monday through Friday) for 10 weeks. Hair was collected before contamination, after contamination but prior to the sweat application, approximately 6 h post-contamination (approximately 4 h after sweat application followed by a drying period), and then weekly for 10 weeks. Weekly samples were collected on Thursday mornings following overnight drying. A schematic of the sampling design is presented in Figure 1. At all points, hair was analyzed and quantitative results were obtained for COC, benzoylecgonine (BE), cocaethylene (CE), and norcocaine (NCOC).

All samples were submitted to analytical laboratories in a randomized blinded fashion with both positive and negative control materials. The three analytical laboratories were solicited by RTI prior to the study. These laboratories were provided the study protocol and provided the opportunity to comment on the study design prior to agreeing to participate. The laboratories conducted all quantitative analyses for the study and were compensated for their analytical work.

All other protocols were performed at RTI facilities, in laboratory space not previously used for handling COC. All laboratory equipment and bench spaces were thoroughly cleaned with alcohol and dried prior to the study, and bench-top blotter paper covers were changed regularly throughout the study period.

Hair selection

Hair used in this study was obtained from hair donations collected by a professional stylist. All hair donations were from young females and had not been subjected to cosmetic treatments such as bleaching, coloring, or permanent wave. Prior to the study, all hair samples were analyzed and determined

not to contain detectable concentrations of drugs of abuse including cocaine. Samples were selected to cover a range of colors from blonde to black. The study was designed to provide an estimate of interindividual variation but did not include sufficient samples to determine differences between ethnic groups or hair color with statistical significance. Table I provides descriptions of each of the hair types used including hair color based on the Schwarzkopf scale (21). Melanin content was estimated as described.

Hair samples were also evaluated by scanning electron microscopy to determine if any visibly obvious differences in the cuticle were present. Hair samples were also examined for excessive wear indications such as missing or grossly broken cuticle. Hair samples were prepared as described in Stout et al. (22). All hair locks were judged to be substantially similar in the extent of cuticle damage prior to use in the study.

Twelve grams of each of the five hair types were used in the study. The locks were maintained loose and were stored loose throughout the study on clean laboratory blotter paper covered with clean filter papers. Hair samples were stored at ambient laboratory conditions of approximately 25°C and approximately 50% relative humidity (RH) with fluorescent lighting.

Total melanin measurement

Hair samples were analyzed for melanin content by a method modified from Kronstrand et al. (23). Pulverized hair (10 mg, 5 replicates) from each hair type was heated at 90°C for 16 h in Solvable™ (PerkinElmer, Rigaweg, The Netherlands), a commercially available aqueous solubilizer. Solvable was selected to replace the Soluene-350 used by Kronstrand et al. (23) for laboratory safety reasons. Absorption was then measured at 500 nm using a Gilford Instruments model 260 spectrometer (Oberlin, OH). An eight-point standard curve was constructed using sepium melanin (Sigma Aldrich) concentrations from 5 to 1000 µg/mL. A linear curve was obtained over this range ($r^2 = 0.9998$) and this curve was used to calculate the total melanin concentration in the hair samples. Results are presented in Table I. A single-factor ANOVA was used to compare the five groups (Excel 2003, Seattle, WA). Melanin concentrations were significantly different ($P < 0.0001$). Hair samples 1 and 2 had significantly less melanin than hair sample 3, which had significantly less than hair samples 4 and 5. Concentrations were consistent with those reported in Scheidweiler et al. (24).

Cocaine contamination

A separate determination of the purity of the COC HCl used in the study was conducted by one of the analytical laboratories. The COC was submitted to the laboratory as a solution in acetonitrile. The COC was determined to have approximately 0.6% CE and approximately 0.1% NCOC.

One 15-mg portion of COC HCl (Malinckrodt, Paris, KY) was weighed out for each of the 5 hair locks. Gloved hands were misted with the synthetic sweat solution described and rubbed together until dry. This reduced static effects from the gloves. The weighed COC was then applied to the gloved hands and rubbed until the COC was no longer visible on the palmar surfaces. At this point, the hair was handled with gloved hands

Table I. Hair Specimens—Subject Demographics, Color, and Qualitative Description of Texture

Hair	Schwarzkopf Color*	Subject Demographics and Texture Description	Mean Total Melanin (µg/mg) (SD)
1	Blonde 9.0	Caucasian female, thin strands	6.6 (5.4)†
2	Light brown 7.5	Caucasian female, thin strands, easily tangled	7.0 (4.5)†
3	Brown 6.5	Caucasian female, slight wave, smooth, thick strands	31.1 (6.6)‡
4	Dark brown 5.5	Caucasian female, slight wave, smooth, thick strands	60.7 (10.5)§
5	Very dark brown 4.0	Asian female, thick, straight, and smooth strands	57.4 (6.2)§

* Color is based on the Schwarzkopf scale (21).

†, ‡, § Indicates groups of samples that were significantly different from the other groups different by a single-factor ANOVA ($p < 0.01$).

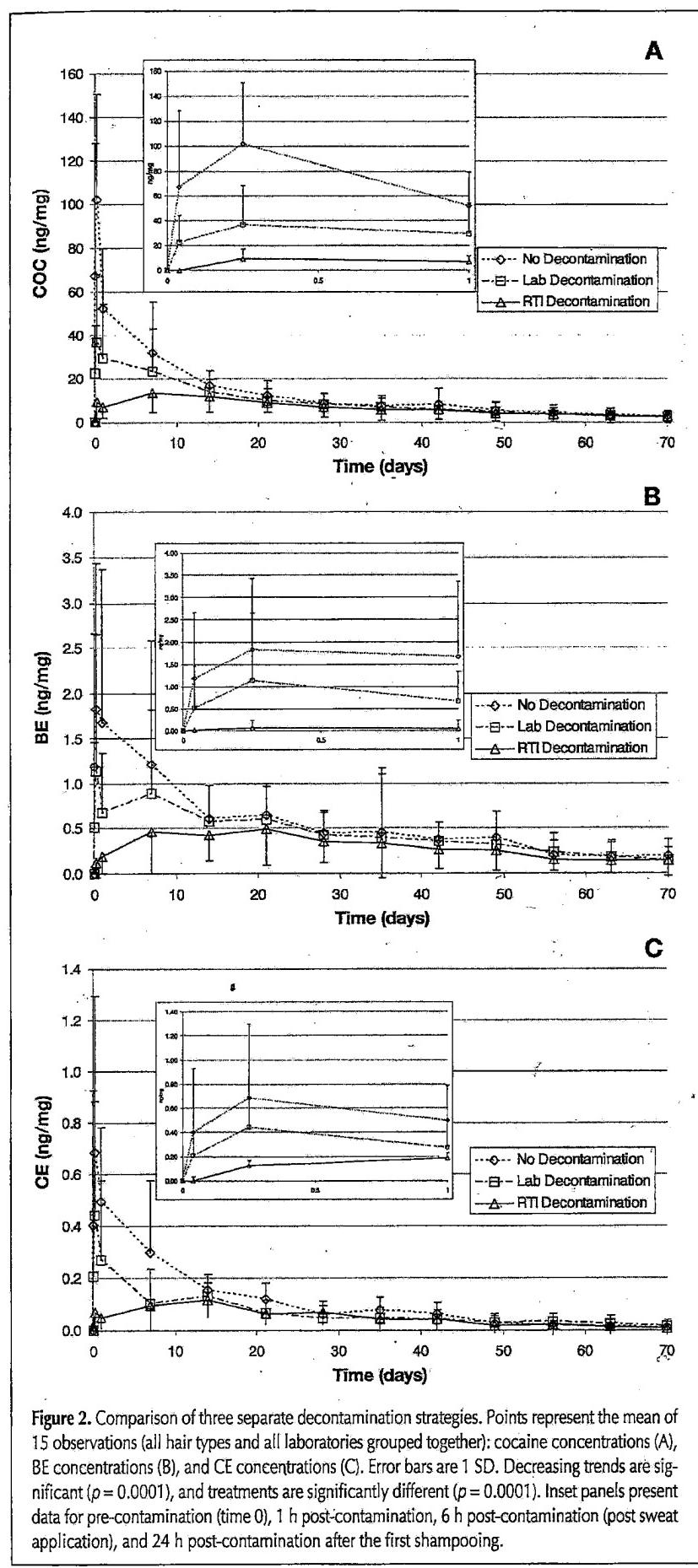


Figure 2. Comparison of three separate decontamination strategies. Points represent the mean of 15 observations (all hair types and all laboratories grouped together): cocaine concentrations (A), BE concentrations (B), and CE concentrations (C). Error bars are 1 SD. Decreasing trends are significant ($p = 0.0001$), and treatments are significantly different ($p = 0.0001$). Inset panels present data for pre-contamination (time 0), 1 h post-contamination, 6 h post-contamination (post sweat application), and 24 h post-contamination after the first shampooing.

for 5 min to distribute the COC throughout the hair lock. The hair locks were then allowed to sit at ambient conditions for 1 h, at which time the first samples were taken.

Sweat treatment

One hour post-contamination but after the first samples were taken, the individual hair locks were treated with a synthetic sweat solution. This solution consisted of 65mM NaCl (OmniPur), 5mM KCl (Malinckrodt), 9mM sodium lactate (Fluka), and 22mM urea (J.T. Baker) as described by Cairns et al. (17). The mixture was modified with the addition of 30 μ L of olive oil per 100 mL of solution to mimic body oils.

Sweat was applied to the entire hair lock using a sprayer. Hair was saturated with the solution to the point of runoff. The hair was allowed to dry on blotter paper at ambient conditions and was completely dry by inspection within 3 h of the treatment.

Daily shampoo treatment

Hair locks were shampooed in the evenings, Mondays through Fridays for 10 weeks. They were wrapped in a gauze wrapping and wet with warm tap water as described in Schaffer et al. (25). Approximately 1 mL of baby shampoo (Johnson and Johnson, New Brunswick, NJ) was applied to the hair, and the hair was massaged for approximately 1 min. The hair was then thoroughly rinsed in warm tap water. The lock was blotted dry using clean blotter paper, and the hair was allowed to dry at ambient conditions. Hair was completely dry by inspection after 3 h.

Hair sampling

At each sampling time point, approximately 400 mg of hair was removed from each hair lock. This was cut into approximately 1-cm pieces and thoroughly mixed. This mixture was divided into three 120-mg portions for each of the three decontamination protocols. Each of these portions was then divided into approximately 40-mg aliquots to send to each analytical laboratory. The hair decontaminated at RTI International was decontaminated as the entire 120-mg aliquot, then subdivided for submission to laboratories for analysis following decontamination.

Decontamination procedures

Samples requiring decontamination prior to analysis were clearly identified by RTI instructions to the laboratories. Blind control materials were included to ensure that a pos-

itive and negative control would be analyzed with samples in all decontamination protocols.

RTI utilized the extended buffer decontamination protocol previously described by Cairns et al. (17). In brief, 120-mg hair samples were shaken vigorously at 120 rpm at 37°C for 15 min in 20 mL isopropanol. Then hair samples were shaken at 120 rpm in 20 mL 0.01M phosphate buffer/0.01% bovine serum albumin (BSA), pH 6 for 30 min at 37°C. The shaker was configured so that the sample tubes traveled a short distance and experienced an abrupt change in direction at the ends of the shake cycle ("bumped" at the ends). This was repeated two more times, followed by two 60-min buffer washes using the same conditions. The hair aliquots were allowed to air dry prior to shipping.

The analytical laboratories all used different decontamination procedures. One laboratory used an extensive aqueous buffer wash. The second laboratory used a brief methanol wash. The third laboratory used two sequential brief washes in methanol.

Preparation of samples for analysis

All hair samples submitted to analytical laboratories were weighed, packaged in foil, sealed in individual plastic bags, and sent by overnight carrier to the laboratories. Negative and positive control samples were randomly inserted with each shipment.

Negative control materials were prepared from each of the five hair locks prior to cocaine exposure. Portions of each hair lock were used as negative controls several times throughout the study so that multiple determinations were made on each negative hair by all laboratories. Control materials were packaged similarly to study samples so as to be blind to the laboratories.

Positive control materials consisted of hair from both known drug users and control hair preparations manufactured in association with RTI's efforts in the NLCP Pilot PT for hair testing laboratories conducted under contract to SAMHSA, HHS. Several different target concentrations in these materials were used throughout the study.

Controls were included in submissions such that at least two negative and two positive controls were sent to each laboratory with each submission. Control materials were inserted in a randomized blinded fashion and submitted with samples to analytical laboratories on a weekly basis throughout the study.

Statistical analysis

All statistical analyses were performed using

SAS (version 9.1.3, Cary, NC). Comparisons of the effects of time, decontamination method, and their interactions were accomplished using linear mixed models (PROC MIXED). Results from the three laboratories were treated as replicate analyses, yielding 15 clusters, 3 per hair type. For the first analysis,

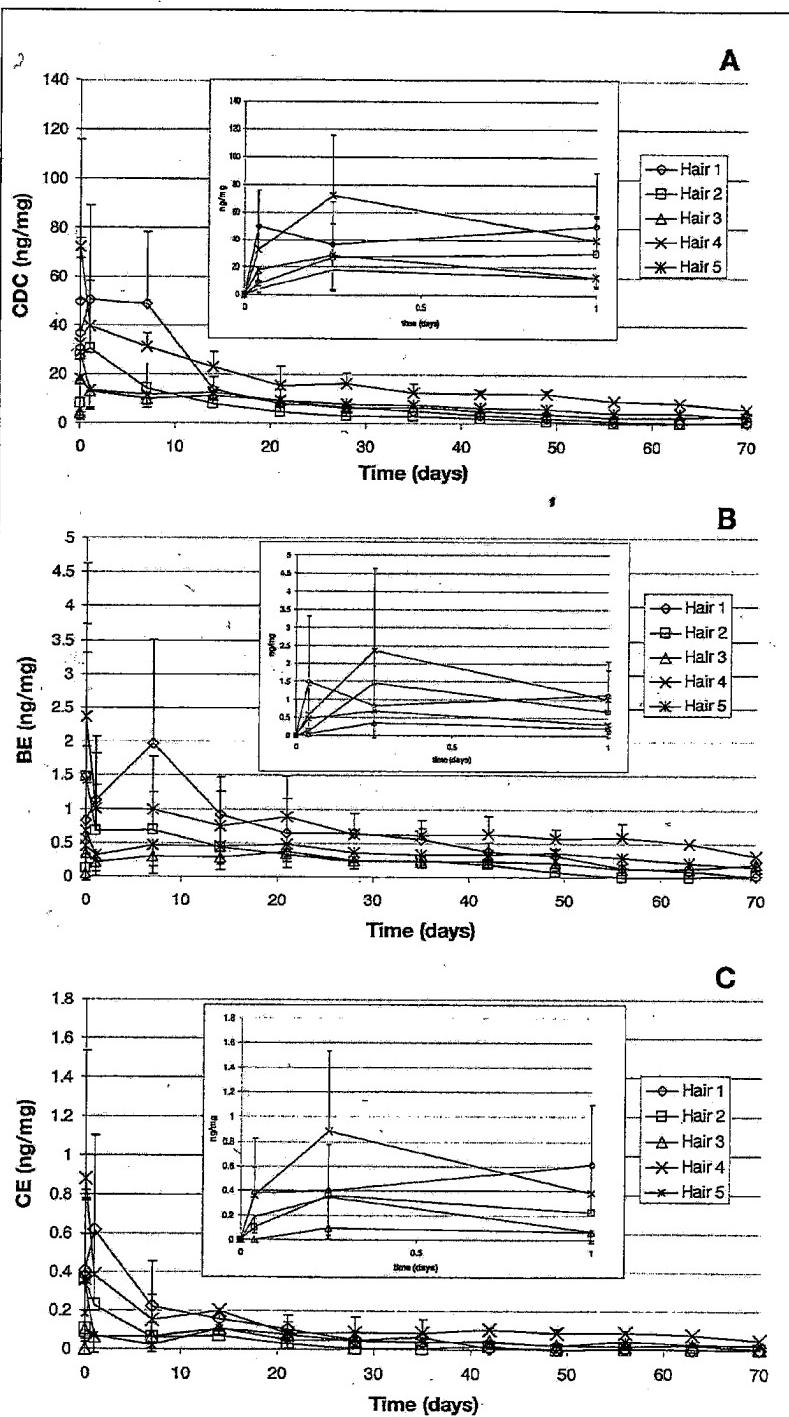


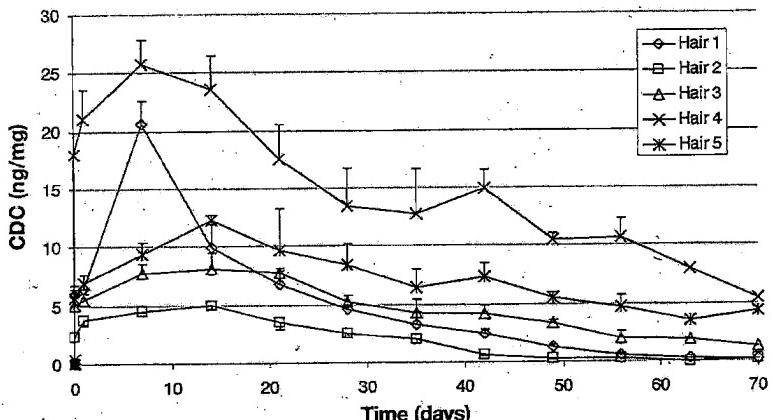
Figure 3. Comparison of five hair types over the study period for the individual laboratory-decontaminated samples (three different decontamination protocols). Points represent mean of three observations (treating laboratories as replication): cocaine concentrations (A), BE concentrations (B), and CE concentrations (C). Error bars are 1 SD. Decreasing trends are significant ($p = 0.0001$). Inset panels present data for pre-contamination (time 0), 1 h post-contamination, 6 h post-contamination (post sweat application), and 24 h post-contamination after the first sham-pooing.

a repeated measures model with doubly repeated measures (two within-cluster covariates, time, decontamination method, and their interaction) was fit to these data. The correlation across decontamination methods was accommodated by fitting a random intercept model to decontamination methods within person, and compound symmetry was used to describe the correlation of observations across time within decontamination

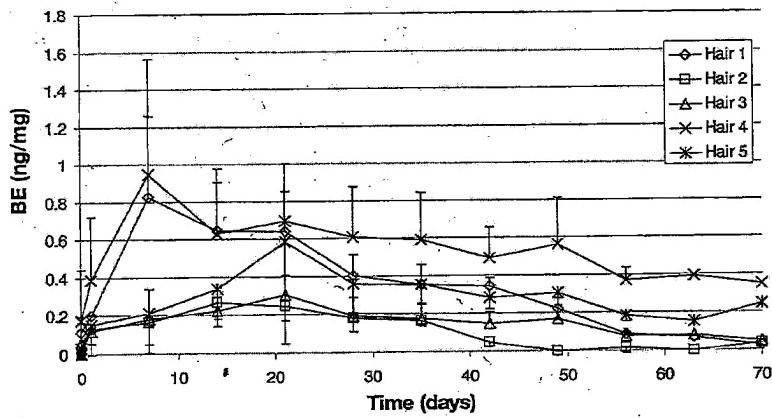
methods. Tukey's method was used to adjust for multiple comparisons among decontamination levels. Statements of significance related to Figures 2 and 3 are derived from this model.

A second analysis was conducted comparing hair types (separately by decontamination procedure). Laboratory results were treated as replicate analyses, resulting in 15 clusters, 3 per hair-type. A repeated measures model with one repeated factor (time) and one between cluster covariate (hair-type) was fit. Compound symmetry was used to describe the pair-wise correlation of observations over time. Tukey's method was used to adjust for multiple comparisons among hair types. Statements of significance related to Figures 4–7 are derived from this model.

A



B



C

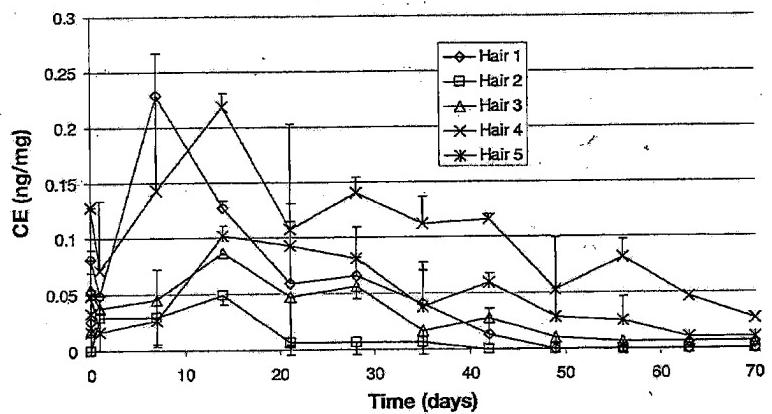


Figure 4. Comparison of five hair types over the study period for the RTI-decontaminated samples (all samples decontaminated with the same protocol at RTI). Points represent mean of three observations (treating laboratories as replication); cocaine concentrations (A), BE concentrations (B), and CE concentrations (C). Error bars are 1 SD. Trends are significant ($p = 0.0001$). No insets included, as early time points are more distinct in these data.

Results

All three laboratories reported results on all hair samples (no missing results). Also, all control materials submitted to the laboratories were analyzed and the reported results were consistent with expected performance. All five hair types had no detectable COC, BE, CE, or NCOC prior to contamination. NCOC results are not presented in the figures as most results were below limits of quantitation. All reported results are above laboratory limits of quantitation. Table II lists the limits of quantitation for the three analytical laboratories.

Figure 2 presents the mean results of the five hair types analyzed by the three laboratories over time by decontamination strategy. Error bars on all charts represent one standard deviation (SD). For all three frames in Figure 2, each point represents the mean of five hair samples with one determination by each analytical laboratory ($n = 15$). Only hair that was decontaminated at RTI at 1 h post-contamination prior to sweat treatment and shampooing had no detectable COC, BE, CE, or NCOC. Hair analyzed without decontamination had significantly greater amounts of COC, BE, and CE than decontaminated hair samples ($p = 0.0001$) until approximately day 21 of the study period. Hair decontaminated at the analytical laboratories contained significantly more COC, BE, and CE than hair decontaminated at RTI ($p = 0.0001$) until approximately day 21 of the study period.

Concentrations of COC, BE, and CE in all decontamination protocols increased after the application of artificial sweat. This was followed by a significant linear decline over the 10-week sampling period ($p = 0.0001$).

Throughout the 10-week period, COC was detected in all hair samples and some hair samples still had detectable BE and CE. All results were highly variable as indicated by the error bars.

Figure 3 presents mean results by hair type for the hair

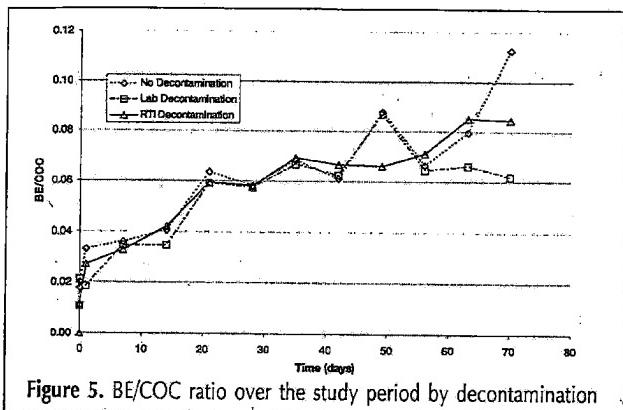


Figure 5. BE/COC ratio over the study period by decontamination strategy. Points are the mean of 15 observations including all hair types and all analytical laboratory results. Error bars omitted as all %CV were approximately 50%. No significant differences detected between treatments. The upward trends are significant ($p = 0.0001$) and linear over the study period.

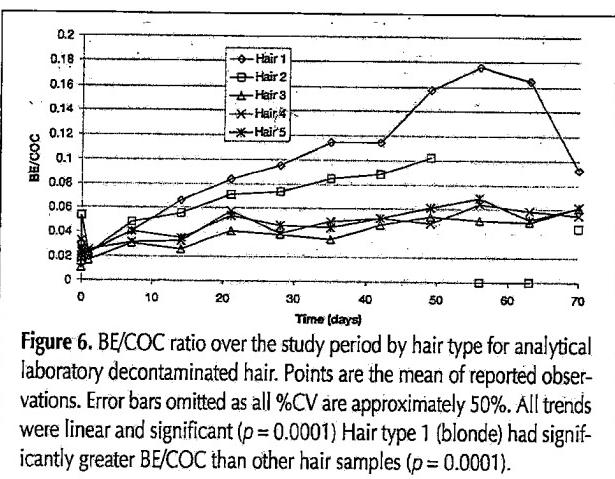


Figure 6. BE/COC ratio over the study period by hair type for analytical laboratory decontaminated hair. Points are the mean of reported observations. Error bars omitted as all %CV are approximately 50%. All trends were linear and significant ($p = 0.0001$). Hair type 1 (blonde) had significantly greater BE/COC than other hair samples ($p = 0.0001$).

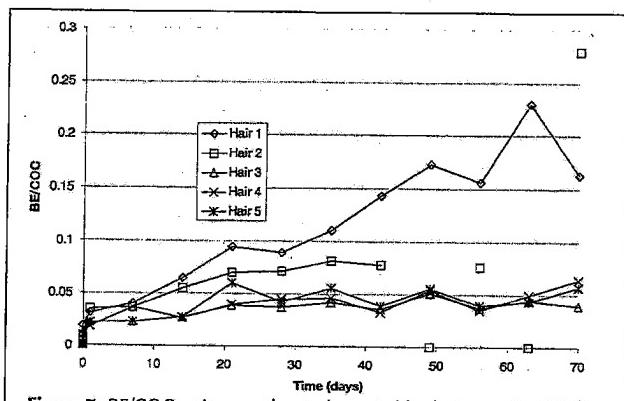


Figure 7. BE/COC ratio over the study period by hair type for RTI decontaminated hair. Points are the mean of reported observations. Error bars omitted as all %CV are approximately 50%. The zero points for hair type 2 are due to BE not being detected by any of the analytical laboratories at those two time points, thus the ratio is zero. All trends were linear and significant ($p = 0.0001$). Hair type 1 (blonde) had significantly greater BE/COC than other hair samples.

samples that were decontaminated by the analytical laboratories. Each point is the mean of the three analytical laboratory results, and error bars represent one SD. Results in Figure 3 for COC, BE and CE in each of the hair types are consistent with Figure 2. A significant linear decrease in COC ($p = 0.0001$), BE ($p = 0.0001$), and CE ($p = 0.0001$) concentrations over time was evident. Interestingly, at day 7, hair type 1 (blonde hair) had significantly higher concentrations of COC than hair types 3 (brown, $p = 0.0005$) and 5 (dark brown, $p = 0.0136$). By day 21, the differences were small or insignificant. BE was not detectable in blonde hair type 1 at days 56 and 63 (indicated by zero points).

There was no apparent simple relationship between concentration and hair color. For example, after day 7, hair type 4 (dark brown) had significantly greater concentrations of COC than all other hair types ($p = 0.0001$). However, hair types 4 (dark brown) and 5 (very dark brown) had similar melanin contents but significantly different ($p = 0.0001$) cocaine concentrations. Again there was large variability in results between laboratories.

Figure 4 presents results separated by hair type for the hair samples that were decontaminated at RTI (decontamination not performed by the analytical laboratories). Results presented in Figure 4 indicate a pattern similar to that found in Figures 2 and 3 characterized by a sharp increase in concentration after the sweat treatment and a significant, linear decrease over remainder of the study period for all hair types ($p = 0.0001$). In Figure 4A, hair type 4 (dark brown) had significantly higher concentrations of COC than all other hair types ($p = 0.0001$). In Figure 4B, hair type 4 had significantly greater BE concentrations than hair types 2 and 3 ($p = 0.0001$ and $p = 0.0001$, respectively). In Figure 4C, hair type 4 had greater concentrations of CE but not significantly at all time points. COC concentrations were the lowest in hair type 2 (light brown). Notably, the variance in results was considerably less as indicated by the error bars than the variance observed in Figures 2 and 3.

Figure 5 presents the mean ratio of BE/COC concentrations for all hair types analyzed by all three analytical laboratories over the 10-week period. Error bars were omitted from these data and %CV for all points was approximately 50%. There were no significant differences between the three decontamination strategies ($p = 0.5919$). The BE/COC ratio rose significantly in a linear fashion ($p = 0.0001$) over the test period indicating an increased concentration of BE relative to COC over time during the study. The mean BE/COC ratio exceeded 5% by day 21 in all hair types.

Table II. Limits of Quantitation for the Three Analytical Laboratories

	COC (pg/mg)	BE (pg/mg)	CE (pg/mg)	NCOC (pg/mg)
Lab 1	20	20	20	20
Lab 2	100	20	100	50
Lab 3	60	15	15	10

Figure 6 presents mean BE/COC ratios by hair types subjected to each individual laboratory's decontamination protocol (each point is the mean of the three analytical laboratory results). Hair type 1 (blonde) had significantly faster and higher increases in the BE/COC ratio over the study period than did all the darker hair samples (when compared to type 2 $p = 0.0150$, to type 3 $p = 0.0018$, to type 4 $p = 0.0103$, and to type 5 $p = 0.0339$). The trend for all hair samples was significant, positive, and linear ($p = 0.0001$) over the study period.

Figure 7 presents mean BE/COC ratios for each of the five hair types subjected to decontamination at RTI (mean of the reported determinations). A significant linear increase in the BE/COC ratio was evident ($p = 0.0001$). Hair type 1 (blonde)

had a significantly greater increase than hair types 3 ($p = 0.0009$), 4 ($p = 0.0014$), and 5 ($p = 0.0022$). The pattern was very similar to that observed in Figure 6. Again, there was no apparent simple relation between hair color and concentration, at least within the hair types tested in the study. The zero points are due to BE not being detected by any laboratory at those time points; thus, the ratio was zero. For hair type 2 at 70 days, the high ratio is due to a very low reported BE result.

Individual hair type results (concentrations and BE/COC ratios) that were not decontaminated are not presented, as there were no additional patterns and the results were consistent with the overall results.

The application of the proposed Federal Mandatory Guideline criteria (26) for designating a hair specimen as positive or negative to the data obtained in this study are presented in Table III. When the proposed criteria of COC greater than or equal to 500 pg/mg, BE greater than or equal to 50 pg/mg, and BE/COC ratio greater than or equal to 0.05 were used to designate an analytical result as positive, 235 of the 585 total analytical results for the contaminated hair aliquots would have been called positive, including those samples that had no decontamination performed. Of the 390 samples that were decontaminated, 148 samples still met the proposed criteria to be called positive. For all hair types, there were samples that would have been called positive by at least one analytical laboratory for almost the entire study period.

Table IV presents the results of applying the alternative proposed federal cutoff of COC greater than or equal to 500 pg/mg and CE or NCOC greater than or equal to 50 pg/mg. This resulted in a total of 303 samples of the 585 total analyzed samples that would have been called positive including samples that were not decontaminated. Of the 390 samples that were decontaminated, 182 samples met the criteria to be called positive. Thirty-four samples had NCOC greater than 50 pg/mg including samples that were not decontaminated. Of those samples that were decontaminated, 20 samples contained detectable NCOC, and 13 had NCOC greater than 50 pg/mg. All samples containing NCOC also had CE greater than 50 pg/mg.

Table III. Number of Days at which the First or Last Positive from Any Analytical Laboratory was Observed Assuming the Proposed Federal Regulation Cutoffs (26)*

Hair	No Decontamination		Laboratory Decontamination		RTI Decontamination	
	First positive	Last positive	First positive	Last positive	First positive	Last positive
1	Day 0	Day 70	Day 0	Day 63	Day 1	Day 56
2	Day 1	Day 49	Day 0.5	Day 70	Day 1	Day 42
3	Day 0	Day 70	Day 21	Day 70	Day 28	Day 63
4	Day 1	Day 70	Day 7	Day 70	Day 1	Day 70
5	Day 1	Day 70	Day 7	Day 70	Day 6	Day 70

* COC greater than or equal to 500 pg/mg, BE greater than or equal to 50 pg/mg AND BE/COC ratio greater than or equal to 0.05. Day 0 represents the hair sample taken 1 h after contamination prior to sweat treatment. Day 0.5 represents the hair sample on the day of contamination after the application of synthetic sweat. Total number of aliquots testing positive by these criteria was 235, including samples that were not decontaminated. Of the samples that were decontaminated, 148 samples met the criteria to be called positive. Laboratory decontaminated samples accounted for 81 of these positives and RTI decontaminated samples accounted for the remaining 67 positives. Total samples analyzed were 585; total samples decontaminated were 390.

Table IV. Number of Days at which the First or Last Positive was Observed Assuming the Alternative Federal Proposed Cutoff*

Hair	No Decontamination		Laboratory Decontamination		RTI Decontamination	
	First positive	Last positive	First positive	Last positive	First positive	Last positive
1	Day 0	Day 42	Day 0	Day 35	Day 0.5	Day 35
2	Day 0	Day 28	Day 0	Day 21	Day 0.5	Day 14
3	Day 0	Day 42	Day 0.5	Day 42	Day 0.5	Day 35
4	Day 0	Day 70	Day 0	Day 70	Day 0.5	Day 70
5	Day 0	Day 56	Day 0	Day 56	Day 0.5	Day 42

* Greater than or equal to 500 pg/mg COC and greater than 50 pg/mg CE or NCOC. Day 0 represents the hair sample taken 2 h after contamination prior to sweat treatment. Day 0.5 represents the hair sample on the day of contamination after the application of synthetic sweat. Total number of aliquots testing positive by these criteria was 303 including samples that were not decontaminated. Of the samples that were decontaminated, 182 met the criteria to be called positive. Laboratory decontaminated samples accounted for 100 of these positives and RTI decontaminated samples accounted for the remaining 82 positives. Total samples analyzed were 585; total samples decontaminated were 390.

Discussion

The results obtained in this study generally confirm the results of Romano et al. (18), who found that COC deposited from the hands remained present on the hair in substantial quantities even after 10 weeks of hygienic treatment and subjection of hair samples to decontamination procedures. The measured concentrations in this study were generally on the same order of magnitude in concentration of COC with Romano et al. (18). These results were consistent with either an increase in the BE concentration developing in situ overtime in the hair, and/or a differential in the rate at which BE and COC were removed from the hair by shampooing and/or decontamination procedures. Nakahara et al. (27) reported that BE in hair was due to hydrolysis of COC deposited in hair, and Wang and Cone (13) found that BE could be deposited into hair from the environment. Cairns et al. (17) and Schaffer et al. (28)

also indicated that BE can form on the hair from parent drug by non-metabolic processes. The analytical laboratories all analyzed controls to determine the potential contribution of analytical production of BE and corrected for any observed analytical artifact.

The statistically significant increase in the BE/COC ratios shown in Figures 5–7, although not specific proof of in vitro formation, was consistent with the referenced reports of BE formation in vitro as well as our experience with manufactured hair testing performance samples stored at room temperature. As Table III demonstrates, this formation resulted in numerous samples being called positive when the proposed federal cutoff criteria of BE/COC greater than or equal to 0.05 and COC of 500 pg/mg or greater were applied. By the COC and the COC/BE criteria, 85 or 44% of the 195 non-decontaminated samples would have been reported positive. By the same criteria, 148 or 38% of the 390 decontaminated samples were positive. The wide differences in the rates at which the BE/COC ratios increased in the five hair samples (Figures 6 and 7), further complicates the development of rules to decrease the number of potential false negatives and false positives.

Additionally, the ratios of metabolites may be influenced by the source of contaminating COC. Illicit COC is known to have widely varying and numerous contaminants and by-products of manufacture, including NCOC, CE, and BE (29). The relative concentrations of these compounds in illicit COC are variable. Bourland et al. (30) reported that 22 "street" COC samples had BE concentrations ranging from 0.2 to 1.9%, EME from 0.5 to 13.7%, no detected CE, and NCOC up to 1.5%. Other investigators report that NCOC ranges up to 5% and CE up to 2% (31). It is known that most, if not all, pharmaceutical COC has some CE present (32).

The COC used in this study was confirmed to have 0.6% CE present in it; 0.6% CE in the COC used in this study resulted in 303 positive samples (including those that were not decontaminated) or 51% of all tested aliquots being positive by the proposed federal cutoff of 500 pg/mg COC and 50 pg/mg CE. Although the number of samples designated as positive by the BE/COC criteria was 235 (including those that were not decontaminated or 40% of all tested aliquots) (Table IV). Of the 195 samples that were not decontaminated, 100% had concentrations of COC above laboratory quantitation limits. By the COC-CE criteria, 121, or 62%, of the non-decontaminated samples would have been reported positive.

Of the 390 samples that were decontaminated, 379 samples had concentrations of COC above laboratory quantitation limits. By the COC-CE criteria, 182, or 46%, of the decontaminated samples were positive. Intuitively, the number of samples designated as positive by the COC and CE criteria would increase as the CE concentration in licit or illicit COC increases. Thus, CE would not be a reliable marker of ingestion at this cutoff because hygienic treatment and laboratory decontamination in this study did not adequately remove it from hair after contamination.

The COC used in this study also had approximately 0.1% NCOC present. Forty-seven (including samples that were not decontaminated) of the hair samples had detectable NCOC reported from at least one analytical laboratory. Of those samples,

20 decontaminated samples had detectable NCOC, and 13 had NCOC greater than 50 pg/mg. Again, with reported illicit COC containing 10–50 times more NCOC, NCOC could be present in the hair because of environmental contamination rather than metabolism. The levels of NCOC observed in this study were too low to be conclusive and require additional studies to determine the potential for this to confound interpretation.

Additionally, wide interindividual variation in the uptake and retention of the analytes in this study, as well as the variations in rates at which the BE/COC ratios increased, did not appear to be simply related to measured melanin content. Blonde hair type 1 had significantly higher BE/COC ratios that rose faster over the study period than did darker hair samples. Hair type 4 (brown), with significantly higher total melanin than hair types 1, 2, or 3, was found to have higher concentrations of COC over much of the study period (Figures 6 and 7) even after decontamination. The sample size in this study was too small to extrapolate these results to the larger population, but the results are suggestive that binding and retention of analytes after environmental contamination is more complex than interaction with melanin alone.

Only hair samples that were decontaminated at RTI almost immediately after sampling at the 1 h post-contamination time point (prior to sweat application) had no detectable COC, BE, CE, or NCOC. This was consistent with the findings of Romano et al. (18) and other authors who appear to have decontaminated the hair very soon after contaminating the hair (17,20,28,33,34). This result is of particular note when compared to hair samples from the same time point (1 h post-contamination prior to sweat application or hygienic washing) submitted to the laboratories. These samples were analyzed by all three laboratories. All laboratories reported significant quantities of COC and some reported small quantities of BE, CE, and NCOC after the individual laboratories had decontaminated these 1 h post-contamination samples.

These hair samples were decontaminated between 5 and 30 days after the contamination event. Thus, in the period between 1 h and 5 days after the contamination event, the analytes became resistant to removal from the hair. This hair was not exposed to either artificial sweat or shampoo.

Hair is a dynamic material of which water is an integral part. In light of the results obtained for the hair samples before they were wet with artificial sweat, it is possible that changes in humidity throughout shipping and storage aided the migration of COC from the surface into the hair matrix with the resulting incorporation being resistant to removal. This phenomenon merits further study and, if confirmed, would further confound discriminating drug positives due to ingestion from those due to environmental contamination.

Although the results of this study were consistent with Romano et al. (18), Wang and Cone (13), and Welch et al. (19), who all found that external contamination was resistant to removal by decontamination strategies, other authors have had different results. Cairns et al. (17) sought specifically to examine the results of Romano et al. (18). They concluded that an extensive buffer wash procedure and the application of a "Wash Criterion" would differentiate contaminated and non-contaminated samples. They attributed the differences in their study from the re-

sults Romano et al. (18) obtained to differences in experimental method. In this study, care was taken to address all of the criticisms cited. Namely, decontamination temperature, hair-to-buffer solution volume ratio, and manner of shaking were matched specifically to the referenced specifications.

To investigate the utility of a "Wash Criterion", RTI selected 65 samples (across the study period) from those decontaminated by the Cairns et al. (17) procedure. As the wash utilized at RTI was that described in Cairns et al. (17), we retained the last buffer wash. The last washes for these samples were analyzed by GC-MS for COC, BE, CE, and NCOC and these results used to calculate the "wash criterion" as described in Cairns et al. (17). In brief, the wash criterion consists of subtracting 5 times the quantity of a compound in the last wash from the quantity determined in the hair and comparing if that resulting value still exceeds the stated cutoff. Ten samples were positive by the HHS-proposed COC and BE cutoffs prior to the application of the wash criterion. After the application of the wash criterion, none of the samples were positive by the COC and BE cutoffs because the ratio of BE/COC was less than 0.05. By the COC and CE cutoffs, 29 were positive by the COC and CE criterion. Twenty-eight of the samples still were positive based on COC and CE criterion after the application of the wash criterion. Even though the wash criterion performed better, samples still would have been reported positive using the proposed federal cutoffs.

Conclusions

It appears that it will be difficult to develop hair PT samples that will demonstrate that all cocaine analytes applied to hair by dry transfer can be removed from hair by current decontamination procedures. Also, the large variability in results from samples decontaminated by laboratories using different decontamination strategies suggests that reinstating the use of these strategies will increase the variability in the current pilot PT program. In addition, the results from this study may have significant impact on further federal policy decisions since these results in general confirmed the findings of Romano et al. (18). External contamination of hair with powdered COC HCl resulted in the presence of COC, BE, CE, and, to a lesser extent, NCOC that was resistant to removal over 10 weeks of model hygienic treatment and laboratory decontamination. The presence of trace quantities of CE and NCOC in the COC used in the study confounded the use of ratios, cutoffs, and other mathematical criteria to distinguish a contaminated sample. This likely will be a greater issue with illicit COC, which has been reported to have up to 20 times the NCOC and 3 times the CE as the COC used in the study. BE also appeared to increase in comparison to COC as evidenced by a significant linear increase in BE/COC ratios over the study period. Within the small sampling of hair types used in the study, there did not appear to be any simple relation of concentrations of COC, BE, CE, or NCOC with total melanin suggesting that the in vitro binding and retention of drugs is a complex function of melanin and other hair components. Contamination of the surface of hair

may result in the incorporation of analytes into the hair without wetting the hair. The addition of moisture to the hair as artificial sweat markedly increased the concentrations of drug in the hair. Once the analytes were absorbed into the hair, they were resistant to removal by shampooing the hair and/or current laboratory decontamination wash procedures.

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Exhibit 10

Untitled

DR. THISTLE (Psychemedics): I have a few comments to make on the RTI study that was reported on earlier regarding contamination.

The study as we saw involved contaminating hair with 15 milligrams of pure cocaine. Firstly, it is important to remember that it is not necessary to remove all the contamination from samples collected for drug testing. Instead, it is only necessary to be able to identify and distinguish samples that are positive, negative or contaminated.

This is no different than with urine testing. It is not necessary to remove adulterants from urine samples, but only to identify when samples are adulterated.

Despite the rather extreme contamination scenario used in the study, as we saw from the slides, when RTI utilized the Cairns wash method practiced by our lab, 65 out of 65 of the contaminated samples tested or were correctly identified as contaminated through the application of the wash criteria and the BE metabolite-cocaine ratio.

RTI's paper demonstrates that effective wash procedures can distinguish even extremely contaminated hair from hair positive due to ingestion when appropriate wash and metabolite drug ratio criteria are applied.

I believe the use of 15 milligrams is not a normal contamination event. It would not be normal to have visible amounts of white cocaine powder on your fingers or hands unless you are in very active cocaine use. It is just as likely that someone who dips their fingers into a pocketful of cocaine or has that amount of cocaine on their hands

s would also touch their mouth or lips. It is even more likely that they would touch your sandwich or coffee cup at lunch if they worked behind a food counter.

This level of contamination would obviously create positive urine results and call into question every cocaine positive urine result in the Federal program, as it requires far less than 15 milligrams to create a positive urine test.

The matrices of hair, urine and oral fluid do not exist in a vacuum. What is a reasonable contamination scenario for any one of these matrices is a reasonable contamination scenario for all of these matrices. I would expect therefore that we would see 15 milligrams of contamination used in future urine and oral fluid studies, or we should acknowledge now that this is unrealistic. Otherwise, as stated previously, this will call into question every cocaine positive urine result in the Federal program.

We mentioned before, we wanted to see about gender bias in hair. We are going to study those things; good idea. I believe we should also study gender bias vis-avis weight perhaps in the urine program that we are conducting. These things don't exist in vacuums. If it is an issue for one, it is going to be an issue for all of them.

In terms of environmental contamination, the difference with hair is, there

Untitled

is a physical barrier and with urine there is not. The study shows that by using proper wash procedures, a laboratory can distinguish samples that have been contaminated. The results in the study were pooled, with correct results being averaged within correct results because of the pooling, but the individual lab results as well as the results of RTI's use of the Cairns wash shows that wash procedures along with BEcocaine ratios are effective and work.

Since that was demonstrated that the BE-cocaine ratios and the wash identified the contaminated samples, 65 out of 65 times according to the chart, the only potential question is the role of cocaethylene as an additional alternative metabolic marker.

Let me clarify this. The RTI slide showed that using the Cairns wash criteria and the BE-cocaine ratios, all the contaminated samples that they tested, 65 out of 65 were identified as contaminated. The only potential issue is the role of CE, cocaethylene, as an additional or alternative marker.

Any potential presence of CE as a contaminant is readily resolved by using a cutoff for CE that is above the potential cocaethylene contamination.

Information used by RTI indicated that cocaine from Peruvian labs appears to have cocaethylene present at a maximum level of two percent. More recently, a thousand samples confiscated in the United States and tested by the Massachusetts State Crime Lab found not even a trace of cocaethylene in the samples. Either way, it is a nonissue.

It should be noted that the cocaethylene contaminated samples in this study were reported by our lab as contaminated. We didn't see that in the data up here.

In fact, we didn't see a lot of stuff in the data up here. I am wondering about that.

But put in the proper perspective, individual lab results of the study demonstrate two things. The Cairns wash criteria works, and the potential presence of CE as a contaminant, if it is an issue at all, is readily resolved. In this type of contamination scenario, I think if we go forward with this and look at what urine and oral fluid do with 15 milligrams of cocaine, you are going to find that hair will be demonstrated to be far safer than urine in this regard.

Some of the other things -- and I didn't want to get into the technical stuff, but when we looked at these slides, we saw bars -- and Peter, maybe you can explain, or Ginny if you are going up, you can explain this -- we saw bars of positive results coming

s
from all the labs.

Those weren't the results that we reported. Our results look something like this, in the samples from July 6. The lab interpretation was reported as contaminated, negative, contaminated, contaminated, contaminated, contaminated, contaminated, contaminated, contaminated, contaminated, contaminated, contaminated,

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contaminated, positive. I could go through all of these, but I think we are going to find that there are only eight samples reported positive that we decontaminated in the entire study. We are wondering where all those positive bars came from.

In one email that was sent, it says in the samples in the RTI experiment that we watched in our lab, the only samples that would have been reported as positive are numbers 238, 351, 399, 459, and I go on for eight more. The rest would have been reported as negative or with the above message that says contaminated.

So anyway, maybe more light can be shed on this, but I think the study as it shows now shows that the wash mechanisms do work, and the only issue left is the CE. That has to be resolved as to whether or not it is an issue at all. If it is an issue, easily resolved.

DR. HILL (Psychemedics): I have been doing hair for something like a quarter of a century.

I wanted to respond to the comment that Dr. Stout said a few times that there is something going on other than color with those five samples. A method that we have been using for years and years is staining with methylene blue. Just intuitively, methylene blue is a water soluble dye that is taken up by porous hair very readily, so we use that as a very relevant indicator of what a drug might do in soaking experiments, for one thing.

We did stain the five hair samples in this study with methylene blue and yes, the first two samples, the blond and the light brown, are highly porous. Generally speaking, in our experience porosity is like the huge indicator of drug uptake. As we published in the JET Journal in 2005, we can take a hair, perm it and stain it before and after perming or have drug uptake before and after perming, and the effect can be 20 fold in terms of increased uptake by porosity effects. So that is one possible explanation of some of the things we saw in this study. Of course, there is only one sample per hair color in the study, so we can't worry too much about the color effects.

In regard to the bar graphs, we saw three labs, a certain number of positives. I am aware that these are strictly using the guidelines and not the wash criteria. But the conclusion that was drawn was that there is no effect of decontamination on the rate of positives. However, that is oversimplification once again.

When we wash our hair, we wash it, yes, and then we use the last wash to determine our wash criteria. You can't call a sample positive or negative in our lab just by cocaine and BE ratios. We use all of our wash information.

Untitled

RTI didn't have that information. They only asked for BE and cocaine and the two incidental analytes that were also there. If they are going to do anything, they could only do by the rules of the guidelines, which is fair enough. I just want to make clear that the reason Bill says we reported those all as contaminated or negative is because we have more information. It is what the washing does for us.

What we did propose as a comment after the proposed guidelines came out some years ago, you cannot do hair testing without a decontamination procedure, and some kind of evaluation of the wash and the remaining drug in the digest.

So we object to saying that decontaminated samples were no different

s from non-decontaminated samples, because there is no comparison in that regard.

That's enough. Thank you.

MR. STEPHENSON: The issue around the hair testing process, what we are doing, I want to keep us on a very positive track of continuing to produce good collaboration and good findings. Based on what we have done here today, I am going to ask members of the Board to think about questions that they would like to have added for the RTI review process and incorporation, and any other members of the public who are here are more than welcome to make some inputs the same way. We will review them and see what we can do about incorporating them, because this is about improving the science and the supportability of this in future situations. I think we need to use all the tools and all the opportunities that are presented to us.

We are learning more and doing more and moving the system faster now than we have for a long time. It doesn't mean that some people haven't done it well in the past, it just means that if we get beyond a single lab, if we get beyond a single entity to do anything in any of these testing areas, we need to look at how to improve performance across multiple participants in the system, and that is what we are doing.

The open session was adjourned at 3:35 p.m.